UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF WASHINGTON

AT SEATTLE

THE NORTHWEST LABORERS-EMPLOYERS HEALTH & SECURITY TRUST FUND, and its TRUSTEES, et al.,	
Plaintiffs,	No. C97-849WD
vs.	
PHILIP MORRIS, INC., et al.,	
Defendants.	

COPY

Telephonic Deposition Upon Oral Examination of

ROBERT D. VERHALEN, Dr.P.H.

Taken at 2025 First Avenue
Seattle, Washington

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DATE: September 29, 1998

REPORTED BY: Kipp R. Hodge, CSR

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I N D E X

EXAMINATION BY: Page

Mr. Withey 5

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EXHIBITS FOR IDENTIFICATION

Number Page

1 - Expenditure Calculation Report, Prepared By Robert D. Verhalen, Dr.P.H. 42

2 - Defendant's Expert Report of Robert D. Verhalen, Dr.P.H. dated July 1, 1997 (Supplied by counsel after deposition.)

3 - (Not yet supplied.)

4 - (Not yet supplied.)

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SEATTLE, WASHINGTON; TUESDAY, SEPTEMBER 29, 1998

8:10 A.M.

--o0o--

MR. WITHEY: On the record.

Before the witness is sworn, my name is Mike Withey on behalf of the plaintiffs. I'm here with Richard Piccioni.

Now, first of all, starting with Mr. Duncan, would the defense attorneys identify themselves, the law firm, and the party they represent.

MR. DUNCAN: My name is Thomas A. Duncan, D-u-n-c-a-n, with Shook, Hardy & Bacon.

MR. WITHEY: Could you identify who you represent, please.

MR. DUNCAN: Lorillard.

MR. WITHEY: Continue.

MS. CLAPHAM: Linda Clapham, C-l-a-p-h-a-m, for Lorillard, at Lane Powell in Seattle.

MR. ZARISKI: Dan Zariski, Z-a-r-i-s-k-i, at Heller, Ehrman, White & McAuliffe, Seattle, representing Philip Morris

MR. O'NEAL: This is Larry O'Neal, Shook, Hardy & Bacon, Lorillard, O-apostrophe-N-e-a-l,

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please.

MR. SEXTON: And this is Terry Sexton, S-e-x-t-o-n, also with Shook, Hardy & Bacon, also representing Lorillard.

MR. WITHEY: Is there anyone else on the line?

MR. THOMPSON: There is William Thompson, also from Shook, Hardy & Bacon.

MR. WITHEY: Is there anybody else on the line?

Well, then there's Dr. Verhalen, I assume.

DR. VERHALEN: Yes.

MR. WITHEY: All right.

Why don't you swear the witness.

--o0o--

ROBERT D. VERHALEN, Dr.P.H., deponent herein, having been first duly sworn on oath, was examined and testified as follows:

--o0o--

E X A M I N A T I O N

BY MR. WITHEY:

Q. Could you identify your name and business address for the record, please.

A. Yes. I'm Robert D. Verhalen. My business

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address is 6867 Elm Street, Suite 300, in McLean, Virginia, 22101.

Q. Doctor, my name is Mike Withey. I represent the plaintiffs, and pursuant to stipulation reached by the parties in this case, this deposition is being conducted telephonically.

I'll have some questions for you this morning. If you don't understand any question or can't hear it, would you please not hesitate to ask me to rephrase it or reask the question.

A. That's fine.

Q. I would therefore understand if you do answer the question, you believe it is a question that you can answer because it's clear enough to answer. Fair enough?

A. Fair enough.

Q. And you understand that despite the fact that we're doing this telephonically, that you are in fact under oath, that anything that you say and I say is going to be transcribed by the court reporter, and that this is a deposition that may be used at the time of hearing or trial in this case.

A. I do understand that.

Q. Doctor, first of all, do you go by "Dr." or

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"Mr."?

A. I go by "Robert" usually, but "Mr." is fine.

Q. Mr. Verhalen, when were you originally contacted by any of the defendants or their law firms with respect to this case?

A. I'm not sure of the exact date, but it was no more than about a month or so ago.

Q. And who contacted you?

A. Mr. Thompson, of Shook, Hardy & Bacon.

Q. Have you done any work with either Mr. Thompson or Shook, Hardy & Bacon or on their behalf before?

A. Yes, I have.

Q. Could you describe the circumstances.

A. I have been reviewing materials for Shook, Hardy & Bacon for the past couple of years in a number of actions involving litigation in which states were looking for restitution for Medicaid funds.

Q. Have you been identified as an expert witness in any of those cases?

A. Yes, I have.

Q. In which cases, sir?

A. In Mississippi, in Texas, in Minnesota, and in Oklahoma.

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Q. Any others?
A. There are others which we've not gotten to the point of deposition yet that I expect to be named at, but at this point no others.
Q. Which have you been contracted for, which other states?
A. Well, I've not actually been contracted for any other states. I've been given some additional materials for most of the states, even the ones I've not been involved in, just for background material.
Q. By "most of the states," you mean the state attorney generals' lawsuits?
A. That's correct.
Q. Have you been hired by Shook, Hardy & Bacon for any other litigation, other than related to tobacco?
A. No, I haven't.
Q. You did not testify in the Minnesota trial, did you?
A. No, I did not.
Q. But you gave a deposition?
A. That's correct.
Q. And you gave a deposition in Mississippi, Texas, and Oklahoma; is that correct?

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A. Not yet. Mississippi, of course, has settled, Texas has settled. I was not deposed in those cases, and Oklahoma I have not yet been deposed on.

Q. So in terms of tobacco litigation, this is only your second deposition; is that correct?

A. That would be correct.

Q. Now, in those other cases, were you asked to review the damage model put forth by the state attorney generals in their Medicaid recovery case?

A. Yes, I was.

Q. Did you have criticisms of each of the models that you've reviewed?

A. That's correct.

Q. Was there any model that you've seen in any of this litigation that you believe was a reasonable estimate of the smoking-attributable expenditures in those states?

A. It's difficult for me to cope with your use of the term "reasonable." They provided estimates, but the reasonableness of those estimates, I guess, is subject to some opinion.

Q. And you had, I take it, one opinion and the experts for the states had another opinion

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about whether they were "reasonable" estimates, then; is that correct?

A. That would be correct.

Q. And this is a matter that's subject to opinion; fair enough?

A. That's true.

Q. Now, have you reviewed any documents specific to this case, sir?

A. Yes, I have reviewed the documents that were prepared by Mr. Roberts and Drs. Dement and -- you'll have to excuse me. Names are always my nemesis. I always have to check back.

Dr. DiFranza.

Q. Any other reports?

A. Yes. All the other reports that were submitted to me by Shook, Hardy & Bacon I looked at, but most of them, as I understand it, were not directly a part of the model.

Q. I'm just asking you which reports you've actually looked at, reviewed, and are prepared to testify about.

A. Well, I've looked at Dr. Weintraub's report. I have looked at Dr. Flanders' report. And that's pretty much about it. The others are the reports that were actually used in the creation of the

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model.

Q. Did you understand there's a relationship between Dr. Flanders' report and the model?

A. Well, Dr. Flanders' report was -- let me ask you to repeat the question. I'm not sure I understood that question.

Q. Well, I guess I'm trying to understand your answer that there were some reports that related to the model and some others that didn't.

A. Well, I didn't say they didn't relate to the model, or at least if I said that I didn't mean that, but they were not actually a part of the generation of the model, the direct generation. It was -- DiFranza and Dement were the two models that I believe had direct input to the creation of Mr. Roberts' model.

Q. And by the way, if at any time Mr. Duncan either writes you a note or brings your attention to any document or any subject matter during the course of this deposition, would you agree to let me know if he does that?

A. I will let you know if he does that, but he did not do that. I was just leafing through my own materials here looking for the names again.

Q. I didn't mean to imply anything. I just wanted

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to get on the record that if he does that, we want you to tell us about it. Okay?

A. Deal.

Q. Thank you.

Have you been retained as an expert in any other union health-and-welfare trust-fund case, other than the case in Washington?

A. No, I have not.

Q. Have you generated any documents in your file there other than the report that you submitted?

A. No, I have not.

Q. How much time have you spent on this matter for Shook, Hardy & Bacon?

A. I would guess perhaps 20 or 25 hours.

Q. Now, what were you asked to do in this case?

A. I was asked to look at the model and give an opinion on whether or not I thought the model would provide the kind of estimates necessary to derive cost figures for smoking-related illness.

Q. Anything else?

A. No, sir, that's it.

Q. Now, we asked you through counsel to produce to us any documents that you relied upon in formulating your opinions, or upon which you based your opinions, and with the exception of

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those articles in the published literature.

Have you identified any such documents?

A. I've identified them all to you in my report.

Q. Other than what is cited in your report, then, are there any other documents that you've reviewed for the purpose of this case that you've relied upon in formulating your opinions?

A. No, there are not.

Q. Now, Mr. Verhalen, I think in your report -- I'm not sure if I have the page number -- you make the statement that smoking causes, quote, unquote, "some diseases," on page 8; is that correct?

A. I'm going to page 8. I didn't think I had made that specific statement, but I would accept the premise that smoking may cause some disease, that's correct.

Q. Well, it says on page 8, "While smoking may be adjudged causal with some diseases," and then you go on and qualify that. Do you see that there?

A. Yes, I do. I'll accept your interpretation of that statement.

Q. What diseases does smoking cause?

A. Well, I think to characterize it as "what diseases does smoking cause" would suggest that

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smoking is the cause, and I think in most cases it's very difficult to segregate out smoking as the only cause for any diseases.

But the diseases which are usually most prominent include several cancers, including lung cancer, and coronary heart disease has been claimed by some to be caused by smoking.

Q. Well, when you say "some" diseases -- first of all, you said "smoking may be adjudged causal with some diseases" -- what are the "some" diseases that you had in mind when you wrote that?

A. Well, in particular, such things as lung cancer, perhaps kidney cancer, and any of the 28 diseases which have been identified earlier in documents by the Surgeon General.

Q. So if we went through a table in the Surgeon General's report that described the kinds of diseases, the 28-some diseases that are identified, you would agree, then, that a cause of those diseases is smoking; is that correct?

A. Not quite the way you phrased it. If you look at my statement, I said, "While smoking may be adjudged causal with some diseases," I'm not talking about, necessarily, in my own interpretation, but by other authorities in the

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field.

Q. Well, I guess, then, I'm asking you which of the 28 diseases mentioned in the Surgeon General's report do you believe are causal, that is, that smoking is a cause of the development of those diseases.

A. Again, I don't want to pick words with you, but when you're asking me which ones I would concede are the cause of the disease, I would say that any of them may be caused by smoking, but they may also be caused by several other factors.

(Discussion off the record.)

Q. Look, I'm asking your opinion here, okay? And I know what others have said, and I know what the Surgeon General's report said, but I'm asking your opinion.

Is smoking a cause of lung cancer?

A. I believe smoking may be a cause of lung cancer, that's true.

Q. Is it more probably than not a cause of lung cancer? Because when you use the word "may," I'm thinking maybe you mean it's possible as opposed to probable.

A. It's probable that in some cases it is the cause, but it's also probable in some cases it is not

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the cause.

Q. I'm talking about from an epidemiological standpoint. Do you understand that from the epidemiological, public-health standpoint, that smoking is a cause of lung cancer?

A. I understand that, epidemiologically, the association between lung cancer and smoking is very high, and it is very likely one of the major causes.

Q. And is that same thing true for cancer of the lip?

A. I'm sorry, did you say cancer of the lip --

Q. Yes.

A. -- or cancer of the lymph?

Q. Lip, l-i-p.

A. Offhand, I'm not sure what the relative risk is there, but I think it may well be fairly high, that's correct.

Q. Is the same true for cancer of the oral cavity?

A. Yes, but perhaps less so.

Q. Is the same true for cancer of the pharynx?

A. Again, you're going down the scale, I believe, of relative risk. As to the extent that it is associated, it may well be a cause.

Q. Well, again, you're using the word "maybe," and I'm

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trying to see if you think more probably than not it is.

Let me just represent to you that the Surgeon General's report identifies cancer of the lip, oral cavity, and pharynx as having a relative risk in current smokers of 27.48. Do you accept that value?

A. I accept the value the way it was computed, yes. I don't necessarily accept the interpretation that it is necessarily causal.

Q. Well, do you believe it is causal based upon that data and those studies cited in the Surgeon General's report?

MR. DUNCAN: Objection; asked and answered, numerous times.

Q. You can answer it, Doctor.

A. If you're asking for my opinion, I believe it may be causal, and that's as far as I can go with it.

Q. So you don't believe a relative risk of over 27 supports the conclusion that it's probably, as opposed to possibly, causal, smoking and lip, oral cavity, and pharynx cancers?

A. I believe that conclusion is probably going a little farther than I would be willing to go. I

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would say that it is a likely possible cause, but I'm not going to go so far as to suggest it's probable.

Q. What other factor would explain a relative risk of smoking and lip, oral cavity, and pharynx cancers showing a value of 27.48 in current smokers?

A. Offhand, I don't know what all the compounding factors would be for cancer of the lip or pharynx, but there are a number of things, dietary considerations and other exposures to which other people might be subjected that might well explain any one of a variety of cancers.

Q. So you're unwilling to say, then, as I understand your testimony -- I just want it very clear -- you're unwilling to say and testify that in your judgment as an epidemiologist, the association between smoking and lip, oral cavity, and pharynx cancers is not "probably" causal in your opinion, it's only "possible"; is that right?

A. That's correct.

Q. And is the association between smoking and lung cancer more probably than not causal, in your

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opinion?

A. It's more probably than it would be with pharynx or lip, I believe, but there are other causes.

Q. Well, Mr. Verhalen, I didn't ask you whether it was more or less than something else, I just asked you, in your judgment, is the association between smoking and lung cancer probably causal?

A. No, I would stick with the notion that it is very possibly causal.

Q. Is there some difference in your mind between "very possibly" causal and "probably" causal? What is the difference?

A. "Possibly" causal suggests to me the fact that there are other possibilities, other causes for the lung cancer. "Probably" causal suggests to me that it's the primary cause, if not the main cause or the only cause.

Q. So if we were to ask the question, "Do you believe the association between smoking and lung cancer demonstrates that smoking is a cause of lung cancer," your answer would be, "Yes, it probably is"?

A. My answer would be yes, it very likely may be.

Q. And the "very likely may be" is less than "probably," then; is that correct?

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A. Correct.
Q. So you cannot say, then, that smoking is probably a cause of lung cancer?
MR. DUNCAN: Object; asked and answered.
Q. You can answer, sir.
A. I think it may well be a cause of lung cancer, but I -- epidemiologically, by itself, does not prove causation.
Q. Well, can you just answer the question, though.
I'll just repeat it again.
As I understand your testimony, you're not saying that the association between smoking and lung cancer is probably a causal factor as opposed to it's likely possible a factor; is that correct?
MR. DUNCAN: Object to the form of the question.
Q. You can answer, sir.
A. I think it may be causal, but it may also not be causal.
Q. Well, I'm asking you whether you are willing to say there probably is a causal association between smoking and lung cancer, and I hear you're saying, no, I'm not saying that, but you're not answering the question directly.

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MR. DUNCAN: Objection; asked and answered numerous times. I think we've been over this a number of times. I think you have his answer.

Q. Go ahead, Mr. Verhalen.

A. I think that smoking may be a cause of lung cancer. That's my answer.

Q. But I'm asking you a different question, sir. Do you think smoking is probably a cause of lung cancer, "yes" or "no"?

A. I can't answer that question with a "yes" or "no."

Q. Well, you're saying it "may be," and you said "may be" means it's possible but it's not probable, correct?

A. That's correct.

Q. So I take it by your answer, by saying all you're willing to say is that it "may be" a cause of lung cancer, what you're saying is that it's not "probably" a cause of lung cancer. Am I correctly understanding your answer, sir?

A. That's correct.

Q. Do you believe it is more likely true than not true that smoking is a cause of lung cancer?

A. I believe it's more likely true that smoking may be a cause of lung cancer.

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Q. Let me ask you this: When I use the word "probably," I'm using that word to mean more likely than not, more likely true than not true, and that's distinct from the word "possible," which means it may be less likely than not true.

Do you understand my definition of "probable?"

A. I'll accept that definition, but then I would say that it's more likely true that it may be a cause of lung cancer, not the cause of lung cancer.

Q. You're getting between the "a" and the "the" and I'm focusing on something else, which is "probable" versus "possible."

Do you believe that the association between smoking and congestive heart disease is "probably" causal, meaning "a" cause, not "the" cause?

A. Of congestive heart disease?

Q. Yes.

A. I don't believe that it's a probable cause. I think it may be a cause.

Q. And then the same question: Do you believe that the association between smoking and cerebral vascular lesions is probably a causal factor?

A. No, I'll not go with "probably" on that. It may be

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a cause.

Q. The same question: Is the association between smoking and chronic obstructive pulmonary disease probably a cause, or is probably causal in the sense of being a cause?

A. No, I will not. I will accept "may be" causal.

Q. And is the association between smoking and esophageal cancer probably a causal factor?

A. I cannot go with "probable." I would go with "may be" a cause.

Q. The same question with respect to pancreatic cancer. Is it the same answer?

A. Same answer.

Q. The same question with respect to cancer of the larynx. Same answer?

A. That's correct.

Q. Same question with respect to cancer of the kidney. Same answer?

A. That's correct.

Q. Now, have you read the Surgeon General's report of 1989?

A. Of 1989, I've read chapter 3.

Q. Have you read any other chapters?

A. I have scanned them at one time some time ago, but chapter 3 is the chapter that I focused on

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because it dealt principally with the epidemiology.

Q. Do you believe that there's a public health benefit that can come out of getting people not to start smoking, or to quit if they've already started?

A. There may well be.

Q. Do you think there probably is?

A. I would guess that there probably would be, yes.

Q. Is that just a guess or is that an opinion based on your years of training as an epidemiologist?

A. It's an opinion based on the data and review of the literature.

Q. What public health benefit can come out of getting people to not start smoking?

A. Well, for one thing here, I can't go so much on the basis of the data as I might go anecdotally, that most of the people who have quit smoking claim to have fewer colds and fewer upper respiratory infections.

Q. Anything else?

A. I think everybody's clothes would smell a lot better.

Q. Any other public health benefits from not starting or quitting, that you can think of right

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now?

A. To the extent smoking may or may not have caused any particular disease condition of the 28 that we've gone through, there would probably be less of that disease.

Q. There would be "probably" less of that disease or "possibly"?

A. I'll accept "probably" or "possibly," either one, on that.

Q. Is there a relationship between the mortality ratio for lung cancer and the age that people begin smoking?

A. Between the mortality ratio of lung cancer and the age at which they began smoking?

Q. Yes.

A. I think it's closer to the amount of years they've smoked rather than the age at which they began smoking, because in any cases people have quit.

Q. You're answering a question that I didn't ask. I'm asking you is there a relationship between the age a person begins smoking and the mortality ratio for lung cancer.

A. I'm sure there is, but I don't recall the numbers.

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Q. And do you believe that that is a significant difference, i.e. between the age one begins smoking and the mortality ratio between people who begin smoking under 15 versus those that begin, let's say, at 25 or older?

A. I really don't know. I don't recall the numbers, as I said. And as to the significance of it, it may or may not be significant. I don't know.

Q. Have you done any work in smoking in public health or human health?

A. No, I have not.

Q. You've not written a paper?

A. That's correct.

Q. You've done no research?

A. That's correct.

Q. And you haven't read chapter 2 thoroughly of the Surgeon General's report, I take it, correct?

A. I have read chapter -- I have read the entire Surgeon General's report, as a matter of fact each subsequent year's report, but in a variety of different contexts over the last few years.

Q. Have you ever made any statement in writing in any paper submitted, abstract, government report, any of your work, any statement in writing that

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addresses whether smoking is a cause of various disease end points?

A. I have not.

Q. Well, are you conversant or do you feel capable of testifying as an expert on the issues of smoking and human health?

A. I do not consider myself an expert on disease and smoking, I consider myself more an expert in the methodology of epidemiology.

Q. Well, do you know if there's a difference in the mortality ratio of smoking and lung cancer for how many cigarettes a person smoked a particular day?

A. There is reported to be a dose-response relationship between the intensity of smoking and disease, that's correct.

Q. Have you yourself ever, in writing, applied the Hill criteria?

A. No, I have not.

Q. I take it you don't consider yourself an expert in the application of the Hill criteria as it relates to smoking and human health; fair enough?

A. That's fair.

Q. Now, are you familiar with the CPS II study relied upon by the Surgeon General in the 1989

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report?

A. Familiar to the point that I'm conversant with the methods that were used to conduct that survey, yes.

Q. Have you read it?

A. Yes, I have.

Q. Do you have it there with you?

A. I do -- oh, wait. No. The CPS II survey itself, no, I do not.

Q. How many people were involved in that study?

A. You mean how many subjects?

Q. Yes.

A. There were more than a million subjects involved in that study.

Q. Do you know of any other epidemiological study that was larger?

A. No, I do not offhand.

Q. Were the results of that study reported out in terms of the statistical significance of the relative risk findings, or mortality ratio findings?

A. I do not believe that the results of that particular survey lend themselves to a competent relative risk statement because of the nature of the sample.

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Q. My question was, in the data reported out, did they show the 95 percent confidence interval?
A. I believe they did, yes.
Q. And for the diseases listed in the CPS II's table that was placed into the Surgeon General's report, do all of those show statistical significance in terms of the relative risks that were reported out?
A. Yes, but one has to accept all of the assumptions on which that report was conducted or was generated before you can really accept those confidence levels. Those confidence levels are fine if you accept the assumption that the sample is representative.
Q. Representative of what?
A. Representative of population other than the specific population which was surveyed.
Q. What problem do you have with the way the survey was conducted, not in terms of whether it could be used in other samples, but the internal validity of that study?
A. With the internal validity of the study, insofar as it represents a million-plus subjects, people age 30 and over, in households with at least one person at least age 45 or older, and

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somewhere between 93 and 97 percent white are probably a valid relative risk, but you cannot extrapolate beyond that to any general population.

Q. Were there other studies, by the way, that were cited in the Surgeon General's report?

A. There were several other studies that were cited.

Q. And have you read those studies?

A. Not all of them, no. I'm not sure. I would have to go back and see which studies are specifically cited in the report, but he puts a great deal of reliance on CPS II.

Q. Well, he cites the Surgeon General's report, correct?

A. Well, that is the Surgeon General's report that we're talking about.

Q. But you understand that there are a number of studies that are cited in the Surgeon General's report, as well, correct?

A. That's correct.

Q. Have you read the Doll and Hill 1956 study of British doctors?

A. No, I have not.

Q. Have you read the Hammond study in 1966 of males in 25 states?

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A. Not that I recall. I may have somewhere in the background, but not that I recall.
Q. Are you familiar with Kahn's study in 1966 of U.S. veterans?
A. I'm not familiar with it, no.
Q. Are you familiar with the results of the Hirayama study in 1967 of Japanese patients?
A. No, I am not.
Q. How about the Best, Josie and Walker study in 1961 of Canadian veterans, have you read that study?
A. I don't recall that study.
Q. And how about Hammond and Horn in 1958 -- they studied males in nine states -- have you read the results of that?
A. Not that I recall.
Q. How about Cederlof, et al.'s study in 1975 of the Swedish, men and women in Sweden?
A. That sounds familiar, but I don't recall.
Q. How about the study by Dunn, Linden and Breslow in 1960 showing the effects of smoking and various diseases in California occupations; is that a study you've looked at?
A. I may have, but I don't recall specifically.
Q. Well, then, is it your opinion that the results

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of the CPS II study are not consistent with the results of those studies, or you have no opinion because you haven't read them?

A. Well, I didn't say that they were not consistent with other studies. What I said was that the methods that they employed left, in my mind, a great deal of doubt that the results of that study could be in any way extrapolated beyond the particular population that was reviewed.

Q. So your testimony is that even though there may be other studies that corroborate the relative risk found in the CPS II study, you're not in a position to testify that the results of those other studies -- strike that.

In what study of any subpopulation have the relative risks found in CPS II been found not to have applied?

A. I'm not sure I understand the question.

Q. Well, you've testified that the CPS II's data is not applicable or generalizable to any other population, and I'm asking you whether there's any study that you're aware of of a subpopulation, a different population, let's say, than was studied in CPS II, which demonstrates that the relative risks of smoking and, let's

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say, lung cancer, or any of the other disease outcomes, was not the same as or within the range found in CPS II.

A. No, I'm not sure that there are any studies that show anything different than that. But my position with respect to the use of CPS II doesn't change simply because the numbers happen to be within the same range.

Q. So you're not aware of any study that has questioned the use of CPS II in any population other than the population that was studied in that sample?

A. Well, I think there have been critiques of CPS II. Offhand, I don't recall the authors of those, but CPS II has been both accepted and critiqued by different groups.

Q. I'm not asking about critiques or acceptance, I'm asking if the results have ever been different by relative risk of any of the diseases in any study that you're aware of of a population different than CPS II.

MR. DUNCAN: Objection as to form.

A. I'm having difficulty understanding the question.

Q. Well, Let me try to break it down.

For instance, was the study of the

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Canadian veterans, that is, a different population than CPS II, did that reveal relative risks that were different, within the range of confidence intervals, than what was found in CPS II?

A. I think that was one of the studies you asked me about earlier, and I don't think I was familiar with it.

Q. The question I'm trying to ask you, sir, is what study was done of a different population than CPS II, the results of which were materially different than the relative risks found within CPS II for smoking and various disease end points? Do you know of any such study?

A. Offhand, I do not, as I sit here, that is correct.

Q. Have you ever read that there is such a study?

A. I'm sorry?

Q. Have you ever read that there is such a study? Have you ever read any articles in the epidemiological literature that says, You know, this other study failed to confirm the relative risk, it found that smoking was not a cause of or did not have an elevated relative risk for various diseases?

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A. I don't recall reading such a study, no.
Q. So is it true that you believe, therefore, that some sort of study must be done of the population of beneficiaries in these trust funds in order to determine whether the CPS II can be generalized to that?
A. Yes, that would be my position.
Q. And that would be true whether we're talking about the beneficiaries of the trust funds or Medicaid recipients or any substudy, you have to do an epidemiological study of them to determine whether the CPS II is applicable; fair enough?
A. That's correct.
Q. Are you familiar with the National Medical Expenditure Survey?
A. Yes, I am.
Q. How many people were involved in that survey?
A. I believe their original sample design called for about 38,000, but they had substantially fewer than that actually participate.
Q. Was that an epidemiological study?
A. Well, I would consider it an epidemiological study, yes. Anytime you're dealing with population numbers, you're dealing basically with

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an epidemiological approach.
Q. Have you ever cited the NMES survey in any of your work?
A. I have reviewed the NMES survey with respect to its relevance to the use in such studies as have been done by the Surgeons General, yes, I have.
Q. In writing?
A. In my reports, that's correct.
Q. And what do you say about it, generally?
A. Pretty much the same thing as I say about CPS II with respect to its applicability to the population that's being surveyed.
Q. Meaning what?
A. Meaning that it -- what we're really talking about is something that's frequently called "synthetic estimation," where you take general populations from larger groups and you try to extrapolate downwards into smaller population groups and draw the same conclusions.
Q. And you believe that would be inappropriate, correct?
A. I believe in most cases it is inappropriate, that's correct.
Q. And it would be inappropriate to do so for both CPS II as well as for the NMES survey, correct?

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A. That's correct.
Q. Could we use the word "NMES" to mean the National Medical Expenditure Survey?
A. Yes.
Q. All right, thanks.
Have you written criticisms of the way that survey was either conducted or designed, or the "limitations" of it, let's say, rather than "criticisms"?
A. Yes, I've talked about the limitations of it in my report.
Q. Could you identify those limitations for us, sir.
A. The study was a bipartite design, that is that it was done in two pieces by separate contractors for purposes of economic convenience and budgetary considerations, which automatically introduced a certain amount of error because you've got different approaches that are being taken by different surveyors in the questionnaires, and that introduces one level of unknown difficulty in considering them as a single data file.
Q. Anything else?
A. Yes, I think that there's a great deal of reliance upon self-reporting of disease

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conditions, and memory decay presents one potential problem.

Q. Why is that a problem in NEMS?

A. Well, in NEMS, for one thing, people would -- the correlation between what people reported as disease conditions for which they've been treated only had a 39 percent correlation with what was reported by their physician, so it's obvious that the data were not very accurate.

Q. Well, that's a pretty low correlation, isn't it?

A. Indeed it is.

Q. Have you seen a correlation that is that low in studies of this kind? Is that as low as it gets I guess is the question.

A. Well, no, in some cases it can actually be lower, but that's a lot lower than I would place much confidence in.

Q. What would be your benchmark or range of benchmarks to place any confidence in a survey like that, what would you like to see in terms of correlation?

A. If I understand your question to mean what would I like to see as correlation between two separate sources reporting on the same question among the same individuals, I would like to see that up

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closer to around 80 or 90 percent.

Q. That would give you some confidence that there's a reliability factor, then, I take it, correct?

A. Well, at least with respect to recall bias, that's correct.

Q. But as to the 39 percent, you don't have confidence in it, I take it.

A. That's correct.

Q. What other limitations were present in the NMES survey?

A. Well, there were a number of them. I'm trying to recall now, because the NMES was not a part of this particular review.

Q. Well, go ahead, do your best to recall any other criticisms or limitations that you found in the survey.

A. I'm thinking.

Q. Take your time.

A. There's a possibility of digital preference in self-reporting, which is that people tend to round -- some people tend to round numbers up and some people tend to round some numbers down when you're talking about different kinds of things. If they're things that they feel positive about, they may round them up, and if

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they are things they feel negative about, they may round them down.

Anytime you're asking people to recall things from the past, you get what I've termed "memory decay."

Q. Anything else?

A. I think offhand there may be others, but without pondering on it a few moments I can't come up with anything else right now.

Q. Well, Mr. Verhalen, I take it the reports that you've written actually have a more complete discussion of the NMES study design and the limitations; fair enough?

A. Correct.

Q. And have those been submitted to the other side in the states attorney generals' cases, like in Mississippi, Texas, and Minnesota?

A. I believe they have, yes.

MR. WITHEY: So Counsel, Mr. Duncan, do you mind providing those reports to us so that rather than having to continue to ask Mr. Verhalen these questions, he can just submit those as the reports that he already has generated on this topic?

MR. DUNCAN: To the extent that you don't

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have any of those reports, I don't see a problem with that.

MR. WITHEY: No, we don't have those, and what we'll do is have the report that Mr. Verhalen drafted in this case marked as Exhibit No. 1 to this deposition, without objection, and then what we'll do --

Q. Well, how many reports did you write, Mr. Verhalen, that discussed your review of NMES?

A. I believe there were three.

Q. Okay.

MR. WITHEY: When I receive them, they'll be supplied to the court reporter and marked as Exhibit Nos. 2, 3 and 4, if that's agreeable.

Q. And do you have copies of them there, sir?

A. With me here, no, I do not.

Q. No, I mean in your office.

A. Yes, I should have copies of those.

Q. If you can give those to Mr. Duncan and have Mr. Duncan then send them to us as soon as possible, we would very much appreciate it, and then they can be made part of the court record. Fair enough?

A. Either that, or I believe Shook, Hardy & Bacon has copies of these reports that have been

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submitted to them and they could just submit them to you directly.

Q. Very well. That's probably easier.

MR. WITHEY: Mr. Duncan, in order to make this record complete and because we have time deadlines, would you be so kind as to Federal Express those out to us and we'll make sure the court reporter includes them as part of the record?

MR. DUNCAN: That's fine.

MR. WITHEY: So we can expect to get those tomorrow, then; is that fair enough?

MR. DUNCAN: I don't know that you'll be getting them tomorrow. See, I'm on the East Coast, and of course it's three hours later, so by the time we get that together, I don't know if it will be today.

MR. WITHEY: Fair enough. If not tomorrow, then certainly by Thursday. Fair enough?

MR. DUNCAN: We'll do our best.

MR. WITHEY: Okay.

(Exhibit No. 1 marked for identification.)

Q. One other question on NMES, sir, and then we'll

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move on: The topic of whether this issue that you've already discussed, about whether NMES can be generalized or used or applied to other subpopulations, do your reports address that issue?

A. They do.

Q. And you've already testified as to the problems attendant to that, but if you could just generally summarize what problems you see in applying NMES to another population, I'd appreciate it. I know it's probably in your report, but if you can just give me a sense of it, I'd appreciate it, sir.

A. Well, the general sense of it is that when you are going to extrapolate downwards from a larger population to a more limited subpopulation within it, you want to be absolutely certain that the parameters of the populations that you're protecting down to are equivalent to or adjustable to those at the upper level. You want to make sure that they are representative of one another as populations. It's just the same as if you are going to extrapolate outwards to another population.

Q. And that's why you felt that it was inappropriate

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for NMES to be cited in the connection with the Medicaid cases the attorney generals have brought?

A. Well, to the extent that the NMES was used in generating the smoking-attributable fractions which ultimately set the level that the states attorney generals were trying to seek, yes, that's correct.

Q. Were the relative risks identified in NMES?

A. Well, yes, the NMES data were used to generate relative risks.

Q. I'm talking about, now, relative risk for various disease end points.

A. They were used to generate relative risk for disease end points, that's correct.

Q. Have you compared the relative risks of the NMES population with those of CPS II?

A. No, I have not.

Q. Do you believe they would be higher, lower, or the same as CPS II as it relates to, let's say, smoking and lung cancer?

A. Without comparing them, I don't know.

Q. Do you understand that people that doctors diagnose with smoking-related diseases, such as lung cancer, chronic congestive heart disease, or

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emphysema, often seek medical attention for those diseases?

A. They often seek medical attention, but whether or not it's for those specific diseases or related complaints I think is open to question.

Q. And you understand that therefore it takes money to pay for the medical care that smokers with these diseases incur; fair enough?

A. Well, as your question is limited to smokers, I would say that anybody seeking treatment for any of those conditions or related conditions, whether they're smokers or not, there would be a certain cost to their treatment.

Q. And you understand in this case that the cost of that treatment is paid by the union health-and-welfare funds, correct?

A. That's correct.

Q. And you understand that the claims data for the expenditures of these diseases, the ICD-9 encodation of these diseases, was paid for by the union health-and-welfare funds, correct?

A. I understand that to be correct.

Q. And you understand that you had access, if you wanted to, to the complete claims records that were provided to the defendants in the fields

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that they requested from the data, correct?

A. They may or may not have been available to me. I didn't ask for them, because when I was called in on this, it was a very, very tight time frame. As I said, I've just been called in on this within the last month or so.

Q. But were you aware that the claims data for these four health-and-welfare funds in the fields requested by the defendants were, in fact, provided to defense counsel?

A. I haven't thought about it one way or the other because of the time frames, but -- so therefore I was not aware.

Q. And I take it you have not reviewed any of the claims data generated from the trust funds in this case, correct?

A. Other than what was reported in Mr. Roberts' model and the Dement and DiFranza materials, I have not seen any data.

Q. You have not asked the defense lawyers in this case, "Gee, you know, I wish we had some data on these beneficiaries to look at their age or look at their status as to whether they're dependents or beneficiaries." You have not asked to look at that data, correct?

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A. No, I have not because of the time frames involved.
Q. I take it, then, if you had three or four months instead of one month, that that might be data you would want to look at; fair enough?
A. I very well would probably have asked for that, yes.
Q. What would you have asked for?
A. I would have asked for the raw data and the questionnaires that were used, if any, to generate answers to any of the questions that have been raised.
Q. Well, do you understand that the data provided was "claims data," meaning the data showing by patient or beneficiary the medical procedure or costs and the expenditure for that cost which was coded by ICD-9? Did you understand that that was what was provided?
A. I didn't have any understanding about what was provided, but I certainly would have asked for whatever information I could get to see whether or not I felt that it was adequate to draw the conclusions that were drawn.
Q. So, in other words, not having access to the data, you have drawn no conclusions about the

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applicability, then, correct?

A. About the applicability of the claims data, that's correct.

Q. Now, in your report on page 12 -- do you have that in front of you, Exhibit No. 1?

A. Yes.

Q. -- you make the point that, "The history of epidemiology includes numerous occasions in which, due to a variety of circumstances, misinterpretations and misrepresentations, the wrong conclusions were advanced"; is that correct?

A. That's correct.

Q. And you cite the "egregious example" of Love Canal and Times Beach, correct?

A. I considered it a particularly egregious example of epidemiology gone wild, if you will.

Q. You are not contending that the Surgeon General's report reached the wrong conclusions regarding the mortality risk of smoking and various cancers and other diseases, are you?

A. I'm suggesting the possibility that there may have been an overinterpretation of some of the data, but without having access to all of the raw data that went into it, I can't say that one

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way or the other. The purpose for this statement was to simply point out that epidemiology is not always correct.

Q. But you're not saying that the Surgeon General's report was incorrect, are you?

A. I'm saying that it may have overreached on some of the interpretations.

Q. Which interpretations did it overreach on?

A. On the direct causation between smoking and cancer and the relative risks, they may be somewhat higher than would be justified when you begin to look at them in terms of trying to generate attributable-risk statements.

Q. When you say they may have been "somewhat higher," have you quantified the degree to which they overstated the relative risk of smoking and various cancers?

A. Oh, I can't quantify that, but the whole notion of attributable risk when you're dealing with chronic conditions is a very difficult one to buy as a bona fide simply because there are many things that go into creating a disease condition.

Some of them are internal to the individual, his genetics and his entire gene pool, some of them are a function of his

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environment, some of them are a function of his social conditions, and some of them are a function of specific exposures to which he may have been subjected.

As a consequence, attribution to any single cause in chronic conditions when there are a variety of potential causal elements is a very difficult concept for me to buy.

MR. WITHEY: Let me move to strike as nonresponsive.

Q. I'm trying to focus you on the relative risk and you're getting into the issue of attributable risk.

What I'm asking you is, if you look at the table which happens to be on pages 150 and 151 in the Surgeon General's report, you said that some of the relative risks there might be somewhat elevated compared to what I guess you believe the true relative risks are.

Did I understand your testimony correctly?

A. With respect to the relative risk in terms of the way they are measured, that's probably a fair representation in the Surgeon General's table 7, I believe you're talking about, that that would be the relative risk, but its meaning in terms of

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causation is overreached, I think, by the Surgeon General.

Generally, these relative-risk figures are ultimately used in the generation of attributable-risk statements, and attributable-risk statements requires an assumption that all else is equal, that is, all other potential exposures are equal.

To that extent, I think that the relative-risk statements themselves do not lend themselves to the conclusion that smoking is the cause of cancer to the -- with the strength of the conviction placed on it by the Surgeon General.

Q. Have you read the 1964 Surgeon General's report?

A. The first Surgeon General's report?

Q. Yes, in 1964. I don't know if it was the first.

A. Yes.

Q. You did read it, though?

A. I have been through it several years ago, yes.

Q. And what conclusion did the 1964 Surgeon General's report reach about lung cancer and smoking?

A. I don't recall the specific conclusion, but I

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think the essence of it was that lung cancer was probably one of the main results of smoking at that point in time.

Q. And did you agree with it when you read it?

A. I didn't have a position one way or the other about it. I was not involved in the smoking controversy. I was involved in -- just as a student back in '64 when that was written.

Q. Let me ask you if you agree with the following statement: "Cigarette smoking is causally related to lung cancer in men. The magnitude of the effect of cigarette smoking far outweighs all other factors."

A. What is the source of that quote?

Q. The 1964 Surgeon General's report.

A. I don't think I could accept that because at that time they hadn't measured all other factors. As a matter of fact, they still haven't.

Q. Do you agree with the statement that "Cigarette smoking is the most important of the causes of chronic bronchitis in the United States, and increases the risk of dying from chronic bronchitis and emphysema"?

A. I don't have a position on that. I don't necessarily agree with it and I don't necessarily

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disagree with it. Again, I don't know the source of the statement. I presume you're talking about the 1964 report again?

Q. Yes.

A. I don't have a position on that.

Q. Thank you.

Now, again, back on page 12, what was believed to be the relative risk of dioxin and the adverse health conditions that were believed to be caused by the exposures to dioxin in the Love Canal?

A. I don't recall. I just recall the situation as I was reading about it, and I knew Vernon Houk at the time, and from time to time in discussions it would come up.

I've not read the report in many years, but it might have been a magnitude of around 3, a relative risk of 3.0. I'm just -- I'm trying to recall. I really don't have an accurate recall.

Q. And what was the confidence interval on that relative risk, do you know?

A. No. I don't recall.

Q. You've stated here that Vernon Houk "regretted having urged the evacuation of Time Beach some

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nine years earlier." Do you see that?

A. Yes.

Q. What is the cite on that? Is that something that he publicly stated or something that he told you privately?

A. That was a personal conversation with him, but I believe it was also public. It was in the press. But at the time I was an adviser to the organization that he was directing at the Centers for Disease Control.

MR. DUNCAN: Counsel, I wonder if when you get to a convenient resting point here, we could take about a five- or ten-minute break.

MR. WITHEY: Yes, we can take a five-minute break. We're almost done, so I'd just as soon take a five-minute break. We'll come back on in five minutes, then. Take a break.

MR. DUNCAN: Okay, thanks.

(Brief recess taken.)

Q. Mr. Verhalen, you're still under oath. Did you have any discussion with Mr. Duncan at the break?

A. No, we didn't, other than he asked me if I would like something to drink.

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Q. You did not discuss the subject matter of your testimony in any way?
A. That's correct.
Q. He did not suggest anything to you in terms of what questions he might ask or that I might ask?
A. We had no discussion whatever.
Q. Thank you.

Now, going back to page 12 -- well, actually I have a question on page 13 of Exhibit No. 1. You've draw some analogy to the Dow Jones Industrial Average.

Do you see that?

A. Yes.
Q. And then you talk about how one would "dig deeply into the individual stock's performance and balance the result of that scrutiny against the risk the retirement fund is prepared to shoulder."

Do you see that there?

A. Yes, I do.
Q. Is there an analogy, then, to our situation? Do you need to dig into the individual beneficiaries' health information in order to make any judgment as to the issues related to the trust funds as a whole?

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A. No, that was not intended, because this particular example was simply to get at the notion, I believe, that before one makes decisions that could have major ramifications on your personal situation, you wouldn't make a judgment on the basis of information that was collected on a broad level for very generalizable purposes, such as the Dow Jones Industrial Average, and make your own investments.

What I simply said here, when I was talking about a retirement fund, I was suggesting that a company, if it were to be making investments on anything other than the specific performance of a stock and were, to the contrary, making those judgments just on the basis of the Dow Jones Industrial Average, it could very well be undercutting the future retirement of their employees. But it had nothing to do with this particular action or the union or anything else.

Q. Well, let me ask you this: If I had a 15-year-old son and that person was trying to decide whether to start smoking or not, or if you had a 15-year-old son and they were trying to decide whether to start smoking or not, do you think

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telling them about the CPS II study and the relative risk there might be useful information for them to know?

A. No, I don't think I would be thinking about the CPS II survey or anything else. I might be thinking only about whether or not they wanted to start up something that they might not enjoy doing at a later time in life.

Q. Well, in the individual decision whether to start smoking or not, or whether to quit smoking, is this data derived from CPS II appropriate to consider?

A. It might be helpful for an individual. I don't know. Most people don't respond to statistics very well.

Q. Well, the question is whether it would be applicable to that individual, would the data from CPS II be generalizable to that individual.

A. No, I don't believe it would.

Q. In other words, if the 15-year-old asked me, "If I start smoking today and continue to smoke for ten years, what are my risks of developing lung cancer," it would be inappropriate for me to refer them to CPS II because it's not applicable to that individual, correct?

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A. No, I'm not suggesting that it would not be appropriate for you to refer them to whatever source you may want to refer them to if you want to influence their behavior.

In my own situation, I told either of my children, when they were making choices in life, that they would make their own choices, and what they have to think of is the upside and the downside of each one of those.

Q. Do you smoke?

A. I do not smoke now. I did smoke.

Q. How long did you smoke for?

A. Roughly 30 years.

Q. What years did you smoke?

A. Probably from the time I was about 15 or 16 until 1977, so -- oh, gosh, 30 years, I suppose.

Q. How many packs a day did you smoke?

A. I have no idea. It varied all over the waterfront.

Q. Why did you quit?

A. I just -- well, at the time that I quit I was smoking cigars, and my wife had been complaining about the smell of cigars, and I just got tired of smoking them, so I quit.

Q. Were you concerned about the health effects?

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A. I wasn't thinking about the health effects one way or the other. I was thinking at the time about how much I enjoyed a cigar.
Q. Do cigars contain carcinogens?
A. Yes, I believe they do.
Q. Were you at increased risk by smoking cigars of mouth cancer or oral cavity cancer?
A. I suspect I may have been.
Q. Do you continue to smoke cigars?
A. I don't smoke at all since 1977. My wife has declared our home a smoke-free zone.
Q. If I were to ask you whether you believe, as a former smoker, you're at increased risk for lung cancer from that smoking history that you had, your answer would be what?
A. I don't believe I am.
Q. And what body of data would you look to as a scientist to determine what that relative risk might be?
A. I'm just looking at my current state of health, and my respiratory condition, my heart condition, my -- the rest of my general health is generally excellent. I'm feeling fine, I get a physical every year, and I'm in perfectly good condition.
Q. Well, do you understand that you could actually

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have lung cancer which is subclinical?

A. Yes, I understand that.

Q. So as good as you may feel, you may still have lung cancer; fair enough?

A. I suspect that's possible.

Q. Now, the question I asked you is what study or what body of work or research would you look to to determine whether you, as a former smoker, are at increased risk of developing lung cancer or other disease processes.

A. Well, if I were inclined to be concerned about whether or not my risks were still elevated, if it were ever elevated at all, in fact, I would be probably looking at the contemporary literature. But I'm not so inclined because I do not feel I'm at greater risk.

Q. In other words, since you don't think you're at greater risk, there's no sense looking at a report to determine what the greater risk may be; fair enough?

A. I have no interest in doing that any more than I have any interest in looking at the risk that I might develop stomach cancer or something as a result of eating red meat.

Q. Let me just go back.

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Are you familiar with the example of John Snow and the determination of what caused the cholera outbreak in the city of London back in the 1800s?

A. Yes, I am.

Q. Now, John Snow didn't take a statistically valid sample of the subset of people in the next city to determine whether the cholera outbreak that occurred in London might be applicable to that city, did he?

A. John Snow was doing what's called a "descriptive survey." He was not doing an analytic survey.

Q. Well, he didn't take any sample of the next city's water, he just made sure they turned the water off so the cholera outbreak wouldn't spread to that city, correct?

A. He didn't even know that it was in the water. What he did was he happened to notice there seemed to be nodes of the disease in the city of London, and he made a spot map, and he began to plot some of those spots, and he noticed they clustered around the wells in the city, and that suggested to him that maybe it had something to do with the wells. He hadn't even hypothesized that it was the water.

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Once he checked with some of the victims and found out that those were the wells in which they, in fact, got their water, he decided it was a good idea to turn those wells off.

Q. But that saved lives, did it not?

A. That saved lives, that's correct.

Q. And the evidence that he had was enough to act on in that case; is that correct?

A. That's correct.

Q. And he yet did not do any survey to determine whether other populations matched the population that was then at risk of cholera, correct?

A. No, but it wasn't necessary for him to, because there were other sources of water to which the people could go, and so he wasn't taking their water away from them, he was simply closing all those particular wells, and people drew their water from wells which had no similar clusters of cholera. And the proof of the pudding was in the reduction of the cholera epidemic.

Q. And would you agree that the proof of the pudding for smoking is that as people either stop smoking or they refrain from starting smoking, that that leads to a decrease in the diseases that are associated with smoking, sir?

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A. It leads to a decrease in the disease, yes, but it doesn't lead to the elimination of the disease.

Q. Now, on page 18 and 19 of your report, you cite a number of studies that compare smokers to nonsmokers; is that correct?

A. That's correct.

Q. Let's just take the used-seat-belts issue. Do you see that one there?

A. Yes.

Q. Does seat-belt use have anything to do with any causal relationship, itself, to any of the disease outcomes that are mentioned in the Surgeon General's report as being associated with smoking?

A. Not specifically, but it is a surrogate for general risk-taking behavior, and I think it's a fair notion, just from the studies that have been done on seat-belt use, that those who don't use seat belts tend to engage in many more risky behaviors.

They care less about their diet, they are much less concerned about their health in most situations they go to than people who tend to wear their seat belts more.

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Q. Well, does this study that you cite, the Jordan and Berry study, say anything about smoking and human health?

A. I would have to go back and look at the study again. It's been a couple of weeks since I've looked at these. These were the first things that I looked at.

Q. Do you know of any study that draws the conclusion that the use or nonuse of seat belts is a risk factor for any of the diseases mentioned in the Surgeon General's report as associated with smoking?

A. There are many studies at this point where seat-belt use is specifically cited as a cause or protectant against any of these diseases.

However, as I've said, it's a surrogate for risk-taking behavior, and risk-taking behavior leads to many behaviors which may be, in and of themselves, putting individuals at greater risk of lung cancer.

Q. Which behaviors?

A. Just the fact that they were greater risk-takers, that they might be less apt to be concerned about other exposures that they may be subjected to. If they happen to be subjected to pesticides and

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they don't wear a face mask, because of their greater risk-taking behavior they are at greater risk of whatever diseases those insecticides may impose on them, and so forth, and that carries pretty much over into the rest of their life.

Q. Do pesticides cause lung cancer?

A. I'm not sure which pesticides may or may not cause lung cancer. I know that there are some that have been cited.

Q. Which ones?

A. I don't know offhand.

Q. What about insecticides, do any studies show insecticides as a cause of lung cancer?

A. I don't know offhand. I just know that there are various chemicals, both pesticides and insecticides, that have been suggested to be causal in a variety of medical conditions, lung cancer among them. I can't cite you a specific study, I'm sorry.

Q. Is it your testimony that the differential exposure of smokers to pesticides or insecticides because they're risk-takers somehow accounts for the 25-fold increased risk of smoking and lung cancer?

A. No. It's my contention that it may well be

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responsible for a part of that.

Q. Which part of it?

A. I don't know which part of it.

Q. Well, then how could it be considered to be a risk factor if you don't know what the relative risk of insecticide or pesticide use is in lung cancer?

MR. DUNCAN: At this time I'm going to object. It's argumentative.

Q. You can answer.

A. I don't know of a study that's been done on it. It may well have been done, but the point is that I do recall having seen reports sometime in the past that there are chemical exposures to people who are in the agricultural field that have been blamed for their conditions, some of which included lung cancer.

Q. Well, are you prepared to say on a more-probable-than-not basis to a reasonable degree of scientific certainty that exposures to pesticides or insecticides is an indicia of high-risk behavior that more probably than not contributes to the mortality ratio found in the Surgeon General's report between smoking and lung cancer?

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MR. DUNCAN: Object as to the form of the question.

A. That was such a complex question, I'm not sure I was able to follow it.

Q. Well, let me say it again, and I'll slow down.

Are you testifying more probably than not to a reasonable degree of scientific certainty that the exposure to either insecticides or pesticides, as an indicia of high-risk or riskier behavior, contributes to the relative risk found in the Surgeon General's report for smoking and lung cancer?

MR. DUNCAN: Same objection.

A. I think it may well. Unless one actually measures for such exposures, one doesn't really know. But again, the possibility exists that this could be a cause for part of the lung cancer -- the relative risk difference.

Q. So, again, you're saying it's possible but not probable; fair enough?

A. I'm saying it's possible, that's correct.

Q. You're not saying it is probable, correct?

A. That's correct.

Q. So what you're raising here, as I understand it, as the high-risk behavior related to

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pesticides or other factors is some theoretical possibilities that you're putting forth, correct?

A. I don't think they're all that theoretical.

Q. Well, you're not prepared to cite any literature that says that this factor, whether it be seat-belt use or some of the other factors here, is a contributing cause of the association found between smoking and lung cancer, or other diseases; is that correct?

A. That's correct. I'm not trying to claim that seat-belt use or risky behavior, in and of itself, is necessarily a cause, but the result of the risky behavior, what you're exposing yourself to, may well be part of the cause.

Q. Now, you say female smokers were more sexually active, according to this Peterson study; is that correct?

A. That's correct.

Q. You've read the study?

A. Yes.

Q. And, of course, sexual activity is not a risk factor for lung disease or cardiovascular disease, is it?

A. Not that I recall seeing. I'm not sure about cardiovascular disease. I don't recall seeing

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any studies on either one of them.

Q. With the possible exception of cervical cancer, can you think of any other diseases mentioned in the Surgeon General's report as linked to smoking that sexual activity would be a risk factor for?

A. No, but again sexual activity may be another indicia of risk-taking behavior.

Q. We've already answered questions about risky behavior, right?

A. I wasn't trying to offer these as mutually exclusive categories.

Q. No, but I just don't want to have to go back and ask you all the risk-behavior questions again.

MR. DUNCAN: Is there a question?

Q. There's another category you put here, "Less participation in athletics." Do you see that?

A. Yes.

Q. What does that mean, that smokers don't participate in athletics as much?

A. That's correct. This may be related to general physical condition and hardiness.

Q. Are you familiar with what's known as the "healthy worker syndrome"?

A. I'm not -- I don't recognize the term.

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Q. How about the "healthy worker effect"?
A. I'm not familiar with the term.
Q. You understand that a number of the beneficiaries in the population that is covered by the trust fund's medical plan are carpenters, laborers, et cetera, operating engineers?
A. That's correct.
Q. Do you understand that those occupations often require physical exertion?
A. Yes.
Q. Would it be your belief that good physical shape in this population would tend to reduce or increase the risk of developing disease end points from smoking?
A. A good physical condition might be inclined to lead to a genuinely -- a generally healthier condition, that's correct.
Q. The question was whether it would affect the relative risk of smoking.
A. It might.
Q. Would it tend to overestimate or underestimate the relative risk of smoking if you had a generally healthier population because of physical exercise?
A. I don't think I'll buy the notion that they're a

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generally healthier population simply because they're involved in an occupation that involves a certain amount of strength and hardiness, because these are all people who might -- also people who might be more inclined to drink to excess. They're not necessarily as healthy in their pursuits off the job as they are on the job. Just anecdotally, I've seen an awful lot of overweight carpenters.

Q. So the issue of the participation in athletics or not, then, has nothing to do with the assignment of relative risk in this case, correct?

A. I won't say it has nothing to do with it. I'm saying that it very well might be another index of hardiness and a generally healthy lifestyle that might lead to a lower risk of disease in general.

Q. As I take it, then, the purpose of this chart here, with the characteristic and citation to a study, it doesn't necessarily lead to the conclusion that the smoking-attributable expenditures were either over- or underestimated in the method employed by the plaintiffs' experts; is that correct?

A. What this was intended to convey was the notion

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that smokers and nonsmokers differ on a variety of different measures, and some of these measures may either independently, in and of themselves, or as a surrogate for some other condition, be related to greater or lesser amounts of disease in -- among smoking populations as opposed to nonsmoking populations.

Q. And, therefore, a greater or lesser amount of expenditures to treat those diseases, correct?

A. Presumably, that's correct.

Q. Now, are you familiar with any studies that examine the issue of confounding --

(Telephonic interruption.)

Q. Hello?

A. I'm sorry, I lost your question.

Q. Yes, so did I.

MR. WITHEY: Did someone just join or leave? Did anybody just join the conversation?

(No audible response.)

Q. The question I have is whether you are aware of any studies that have looked at CPS II to determine whether any of the confounding variables might explain or alter the results of the relative risks found in that study.

A. As I sit here, I'm not, just off the top of my

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head, aware of any, that's correct.

Q. Have you not read the Battelle study?

A. The Battelle study was in here, but I don't have the total issue of it. It's just part of it that's in here.

Q. Have you read it?

A. I've read what I have, but it's not complete.

Q. What do you have?

A. I have the first few pages and the last few pages. The rest of it just wasn't in the package.

Q. Who gave you that?

A. I got this from Shook, Hardy & Bacon as a large package. It apparently just didn't copy.

Q. When did you get it?

A. Pardon me?

Q. When did you receive it?

A. Probably a couple or three weeks ago.

Q. Did you ask for the full copy of the report?

A. I have not, again, because of the limitations on time.

Q. So I take it you're not prepared to discuss the significance of that report; fair enough?

A. That's correct. As a matter of fact, I can't even find it right now.

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Q. Well, have you received any other materials? I thought I had asked you this question before: What materials have you received from Shook, Hardy & Bacon? And you've described the expert reports.

A. Yes, and that was, I think, a part of the appendix to one of the reports.

Q. All right.

A. I'm unable to lay my hands on it right now. I'm leafing through here looking for it.

Q. That's all right. Since you're not prepared to discuss the report, I'm not going to ask you about it.

Do you anticipate supplementing your report?

A. It depends on how much time there is between now and trial whether or not I'd be able to do any more work on this.

Q. Do you plan on doing any more work between now and October 9th?

A. No. As a matter of fact, I'm going to be unavailable from the day after tomorrow through the 7th.

Q. Through when?

A. Through the 7th of October.

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Q. Have you discussed any additional areas of work with any of the lawyers in this case?
A. No, I have not.
Q. Let's go back to your chart again on pages 18 and 19.
A. All right.
Q. What I want you to do, for each of the characteristics that you've identified, I want you to identify the smoking-related disease or diseases that are implicated.
A. These were not to be representative of anything that is indicated by the condition that appears in the left-hand column. These are simply characteristics that differ between smokers and nonsmokers without respect to disease.
Q. You previously testified that as a result of these characteristics, a person may be at higher risk or at lower risk, depending upon the factor, but I guess, by the same token, there may be no effect whatsoever on the risk of smoking, correct?
A. That's entirely possible. If you read the paragraph directly above the table, the second sentence in that paragraph, I state that many of the differences may themselves account for a

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considerable amount of what is otherwise classified as smoking-related disease in populations, and I'm not sure it's possible to identify which, if any, smoking-related condition would be related to any of these. It's just the ways in which smokers and nonsmokers differ.

Q. Hold on one second. I think I'm just about done. Do you mind just waiting for a minute or two?

A. No, that's fine.

(Discussion off the record.)

Q. Just a couple more questions and we'll let you go on your way.

Are you aware of any changes in the classification of either tobacco or nicotine dependence or addiction as a disease entity incorporated into the tenth revision of the ICD-10?

A. No, I'm not familiar with it.

Q. Is your role in the tenth revision based primarily on the accident part of that ICD classification rather than the disease?

A. That's correct.

Q. You've published how many papers in the peer-reviewed medical literature?

A. (No audible response.)

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Q. Hello?
A. Yes.
Q. I didn't hear the answer. We didn't hear it on this end.
A. I'm sorry. I think only a couple.
Q. How many?
A. A couple. Two.
Q. Two. All right. And one was about ATVs, all-terrain vehicles; is that correct?
A. That's correct.
Q. And that was in the bulletin of the New York Academy of Medicine?
A. That's correct.
Q. And that's a peer-reviewed journal; is that correct?
A. Yes, it is.
Q. Do you know who peer-reviewed this? Well, you wouldn't know that, would you?
A. I don't.
Q. You make a point in the article about the fact that children below age 16 may often use poor judgment in using these vehicles; is that correct?
A. That's correct.
Q. Would you agree generally that children under the

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age of 16 are not of sufficient maturity and judgment to decide whether or not to smoke?

A. No, I don't think you can pick a particular age and say that anybody above or below a particular age, with any degree of confidence, is capable or not capable of doing an awful lot of things.

Judgment tends to decrease as you go down in age, but I'm not sure I would pick 16 as the age. It might be 12 for some people, it might be 20 for others.

Q. So you think there is a 12-year-old in the United States today that can make a mature judgment about the risk of smoking.

MR. SEXTON: I'm going to object to the question as lacking foundation.

Q. You can answer it.

A. I don't have any way of knowing whether or not there is anybody of any particular age that would be able to make a mature judgment about smoking. Mature judgment is a judgment call, and that's going to vary on the basis of the age of the individual and his developmental -- and his development.

Q. Is there any generalization you could reach as to whether individuals, let's say, under the age of

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16 versus over the age of 25 in general are more likely to be able to make a judgment as to whether to start smoking, including considering the future or present health risks of that endeavor?

MR. SEXTON: Same objection; lack of foundation.

Q. You can answer.

A. I could offer you a personal opinion.

Q. Please do so.

A. My personal opinion would be that the older one is the more likely one who would be able to make a mature judgment on anything in his life than a younger person.

But exactly where that cutoff is, I don't know. As I said, I believe there are 12-year-olds who are far more mature than some 20-year-olds.

MR. WITHEY: All right. I have nothing further.

Tom, I would very much appreciate getting those reports as soon as you can get them to us. It's presently about 1 o'clock East Coast time. If you have those there and could Federal Express them out, we have a limited time frame for

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getting the matters submitted to Judge Dwyer. Our motions are due, now, next week.

MR. DUNCAN: I'll get right on that.

MR. WITHEY: All right. Thanks so much.

MR. DUNCAN: Before we go, I need a written transcript, a Min-U-Script of the deposition, and also an ASCII disk.

MR. WITHEY: We will take a copy.

(The deposition concluded at 10:05 a.m.)

(Signature was reserved.)

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C E R T I F I C A T E

STATE OF WASHINGTON)
) ss.
COUNTY OF KING)

I, the undersigned officer of the Court, under my commission as a Notary Public in and for the State of Washington, hereby certify that the foregoing deposition upon oral examination of the witness named herein was taken stenographically before me and thereafter transcribed under my direction;

That the witness before examination was first duly sworn by me to testify truthfully; that the transcript of the deposition is a full, true and correct transcript of the testimony, including questions and answers and all objections, motions, and exceptions of counsel made and taken at the time of the foregoing examination;

That I am neither attorney for, nor a relative or employee of any of the parties to the action; further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially interested in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and seal this 5th day of October, 1998.

KIPP R. HODGE, CCR
NOTARY PUBLIC, in and for the State of Washington, residing at Poulsbo.
My commission expires:
August 10, 2002.

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A F F I D A V I T

STATE OF WASHINGTON)
) ss.
COUNTY OF KING)

I have read my within deposition, and the same is true and correct, save and except for changes and/or corrections, if any, as indicated by me on the "CORRECTIONS" flyleaf page hereof.

_____
ROBERT D. VERHALEN, Dr.P.H.

SUBSCRIBED AND SWORN to before me this _____ day of _____, 1998.

_____
NOTARY PUBLIC, in and for the State of Washington, residing at _____.
My commission expires: _____.

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REPORT ON CALCULATION OF EXPENDITURES FOR
TREATMENT OF SMOKING-RELATED ILLNESS
BY THE NORTHWEST LABORERS-EMPLOYERS
HEALTH & SECURITY TRUST FUND

RECEIVED
SEP 21 1998

Prepared by

Robert D. Verhalen, Dr.P.H.
September 10, 1998

Stritmatter Kessler
Whelan Withey

QUALIFICATIONS

My name is Robert Donald Verhalen. I currently reside in [DELETED] I am President of Verhalen & Associates (VAssoc), a consulting and litigation support firm. VAssoc is built around my 22 years as director of all epidemiology functions of the U.S. Consumer Product Safety, first as Director of its Bureau of Epidemiology and later as Associate Executive Director of the Commission. My Curriculum Vitae which appears at Appendix A, details my background and experience in a systematic format.

I received my Bachelor of Arts degree from the State University of Iowa at Iowa City in Zoology (with a concentration in Parasitology) in August 1963. Following a year with a local public health department in Northern Illinois, I earned my Masters Degree in Public Health from the Department of Health Administration at the School of Public Health at the University of North Carolina, Chapel Hill (UNC-CH) in August 1965.

After roughly a year and a half with the Georgia State Health Department, and nine months at the North Carolina Highway Safety Research Center, I entered the doctoral program in the Department of Epidemiology at the UNC School of Public Health. There, while working for two years as an instructor in the Department of Health Administration (and concurrently for the second year of that appointment, as Task Force Chief on a National Presidential Study

EXHIBIT
1
Verhalen
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Commission , The National Commission on Product Safety (NCPS), and then as an Epidemiology Branch Chief at the Food and Drug Administration (FDA), I earned the Dr.P.H. degree in Epidemiology in May, 1972. As Task Force Chief at the NCPS, I led the team responsible for assessing the quality of national data on produc.-related trauma then extant among Federal agencies, and undertook the development of a system to collect national data to meet the analytic needs of the Commission. The data collected in the pilot system I created provided the Commission with information sufficient to convince the Congress and the President of the need for a permanent Federal agency to further develop the data collection capability necessary to amass nationally representative data on some 15,000 different consumer products, to analyze those data and to promulgate regulations to ameliorate what was then, and remains the leading cause of death among Americans for the first half of their lives: unintentional injuries.

In 1970, the Bureau of the Budget (now, Office of Management and Budget) in the White House directed my transfer with key members of my staff to the FDA where I led the development of a nationally representative system to gather product-related injury data with a previously unavailable degree of accuracy and timeliness: the National Electronic Injury Surveillance System (NEISS).

Section 4(g)(1) of the Consumer Product Safety Act (PL 92-573) which created the U.S. Consumer Product Safety Commission (CPSC) in October 1972, established five statutory executive positions in the Agency, one of which was Director of Epidemiology. Organizationally, this position reported directly to the Executive Director and served as a principal advisor to five Presidentially appointed Commissioners. I was selected by the

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Chairman of the Commission, appointed to this post and assumed responsibility for all CPSCs' population based scientific study when CPSC opened its doors in May 1973. I served as the Agency's Director of Epidemiology until my retirement from federal service in April 1995.

While serving as CPSC's principal survey scientist, I directed the continued refinement of the NEISS to its present status as the preeminent ongoing trauma surveillance system in the Federal Government. Even today, this system, which has been copied by several foreign governments, serves several other federal agencies including the FDA, The Department of Transportation (DOT), the Environmental Protection Agency (EPA), The Centers for Disease Control (CDC - two units, the National Institute for Occupational Safety and Health [NIOSH], and the National Center for Injury Prevention and Control [NCIPC]), The Department of Housing and Urban Development (HUD), and the Department of Justice (DOJ). These interagency alliances not only met critical data needs of many of each receiving agency's programs, but they saved millions in tax dollars by obviating the need for each agency to develop and operate ad hoc systems to meet their analytic program requirements.

In 1973, following appointment as CPSC's representative to the Working Group on Fire Data Analysis for the International Standards Organization (ISO), I was elected Chairman of that twelve-nation group and spearheaded the development of consensus standards for the analysis of fire statistics among member-nation scientists. Later, In the late seventies, I was appointed to the Epidemiology Working Group of the Interagency Regulatory Liaison Group (IRLG), a group of scientists charged with responsibility to create standardized methods and criteria for the promulgation of national standards and regulations at FDA, EPA, CPSC, the Department of Labor's Occupational Safety and Health Administration (OSHA) and the

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Department of Agriculture's Food Safety and Quality Service (FSQS). I was elected Chairman of this group and led the creation of the "Guidelines for Documentation of Epidemiological Studies," designed to improve the ability of these regulatory bodies to assess the quality of science employed in studies submitted in support of regulatory action.

From the late seventies until 1990 I served on the Interagency Committee of Federal Executive Scientists advising on the preparations for the 1980 and 1990 Decennial Census of the Population . From the mid-eighties until around 1990 I served as a member of the U.S. Study Committee of the World Health Organization (of the United Nations) on preparation of the 10th Revision of the International Classification of Disease and Accidents (ICDA). During my 25-year career as a government scientist I have been asked upon several occasions to consult with scientists and other officials representing foreign governments as they endeavored to develop surveillance systems to permit the study of injuries in their own country, e.g., Europe's Organization for Economic Cooperation and Development (OECD), the Commission of European Communities in Brussels, the Nordic Council of Ministers, Japan, Canada, Australia and the United Kingdom.

Upon retiring from federal service in April 1995, I opened Verhalen & Associates, a consulting firm created to assist private parties in accessing, understanding and using public data.

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INTRODUCTION

My testimony and opinions will be based upon my academic training, twenty-five years as a practicing epidemiologist, the scientific literature on issues relating to methodological aspects of population based research and literature on illnesses associated with smoking. In addition I have reviewed literature surrounding the surveys and models employed by scientists endeavoring to estimate smoking attributable health care costs paid by Northwest Laborers-Employers Health and Security Trust Fund et. al. (NLEHTF).

I have also reviewed the Report of the Advisory Committee to the Surgeon General, 1964 and the Reports of the Surgeon General for 1996 and 1998, the Behavioral Risk Factor Surveillance System (BRFSS): Methods, Procedures and Reported State Data, and the American Cancer Society Cancer Prevention Study II (CPS II).

In addition I have reviewed the Supplemental Response to Defendants' Requests for Production, Admission and Interrogatories regarding the Plaintiff's Damage Model, material submitted by Dr. David B. Thomas on May 29, 1998, and the expert reports of Dr. William S. Weintraub (6/3/98), Dr. W. Dana Flanders (undated), Dr. John M. Dement (A Model for Application to Union Health Funds in Washington State - undated and Occupational Risk Factors for Non-Malignant Lung Diseases - undated), the meta-analysis by Dr. Joseph R. DiFranza (Estimated Proportion of Childhood Diseases attributable to the Use of Tobacco - undated), the Final Report of Battelle on Smoking Attributable Mortality: Control for Confounding (February 1, 1997), and the report prepared by Stanley A. Roberts (Smoking Attributable Expenditure Calculations and Opinions in Northwest Laborers-Employers Health and Security Trust Fund et. al. v. Philip Morris, Inc. et. al. - June 5, 1998).

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A listing of principal articles and documents I also reviewed, not cited specifically above, is attached (Appendix B). My review of plaintiffs' material is necessarily ongoing because of the recency of its availability and I may supplement this report as my review of these and other documents, including those yet to be produced by the plaintiff, are made available. I may also rely on the work and opinions of other experts in this case, and/or offer testimony in rebuttal to plaintiffs' witnesses.

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SUMMARY OF OPINIONS

- Epidemiology has limitations in the study of disease etiology and in the attribution of risk.
  - The concept of attributable risk cannot be readily applied to situations with complex, intertwined, multi-causal associations , and long-latency effects.
  - Because of the large number of known and unknown risk factors (confounders) for diseases classified as smoking-related, and the unidentified interactive relationships between these factors, the simplistic concept of attributable risk is inadequate to ascribe "cause" to any single factor.
  - At times, epidemiologic relationships that appear straightforward and plausible turn out to be unconnected.

- There are logical and scientific flaws, from an epidemiological viewpoint, in the model used by the NLEHTF to compute the attributable cost of smoking-related disease..

- The population of the CPSII sample differs materially and substantially from the NLEHTF population.

- Smokers differ from non-smokers in many ways which have nothing to do with the use of tobacco, but which do impact on their health and the degree to which they use the health care system..

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- At times, when appropriate conditions exist, large area data can be projected downward and used as relevant in smaller, more limited areas. These conditions do not exist with the surveys the NLEHTF is using in its damages model.

- While the physiology of disease may remain the same nationwide, exposure to alternatively causal conditions do not. These are more often a function of factors such as geography, industrialization, urbanity, climate, culture, stress, and societal proclivities.

- While smoking may be adjudged causal with some diseases, the notion of quantifying smoking-attributable expenditures for diseases only "aggravated" by smoking is unsound.

- Mr. Roberts' certification that the process by which he has estimated "smoking-attributable health care expenditures produces reasonable, but conservative results" is unjustified.

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BASIS FOR OPINIONS

EPIDEMIOLOGY'S LIMITATIONS

Epidemiology is the basic science of public health medicine. While its roots lie in the study of communicable disease epidemics, the past half century has seen a transfer of its application to the study of noncommunicable diseases as these grew to comprise a greater and greater share of the health deficits faced by human populations.

There can be little doubt that the turn of public health interest from infectious diseases to noninfectious diseases was accommodated by an appreciable change in epidemiologic methods, if not principles. Whereas early epidemiology involved the description of acute outbreaks of infectious conditions in a community (e.g., the classic "epidemic" pattern of nothing to something), contemporary epidemiology redefines epidemics to include the occurrence of a group of similar illnesses clearly in excess of normal expectations in the community. This requires knowledge of disease frequency and distribution during both epidemic and nonepidemic times, both in the referent population and in other populations. The epidemic growth of some chronic conditions, such as coronary heart disease, can be so slow as to conceal its very presence as an epidemic, as well as its enormity, from the populace of the community for many years. Because of this slow growth, and the latency period between relevant exposures and the clinical manifestation of diseases, one of the most challenging purposes of epidemiology is the identification of those components of causation that permit the development of effective preventive measures. *These are of course the same components which are necessary to compute the attributable risk fractions integral to the NLEHTF model.*

The issue of causation, central to any epidemiologic inquiry, is also the most complex issue one faces when considering noninfectious chronic diseases because of the variety of

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associations one generally encounters. Where some of these associations may be causal (e.g., nerve damage following exposure to a particular pesticide), others may be non-causal but closely linked to a causal element (e.g., farming as an occupation). In such a case, the latter (occupation as a farmer) would be termed confounding. *It is critical to note here however that while the occupation classification may itself be a confounder, it also indicates the serious likelihood of additional unmeasured exposures to other potential causes of the condition under study.*

ATTRIBUTABLE RISK

Roberts' estimates for the NLEHTF on the cost of medical care rely heavily on the concepts of attributable fractions and attributable risk. These concepts, however cannot be indiscriminately applied to situations with intertwined multi-causal associations without some peril of overstating the degree to which "risk" is equated with "cause.". The epidemiologic concept of attributable risk, while flexible to the extent that it may apply to accidental injury as readily as to contagious or chronic disease conditions, requires for its computation, data on the incidence or prevalence rates of specific conditions among both exposed and non-exposed individuals in a population. *It is of critical importance to remember that a computed risk figure is no more than an estimate of the likelihood that a particular exposure (or set of exposures) might have been causal with respect to some portion of the observed condition.* Almost every chronic condition has a background rate for which no known exposure to some potential cause, or set of causes can be demonstrated. Unless one actually measures the degree to which these other known confounding variables are present in the population under study, one can only "estimate" the degree to which each of those confounders (which presumably *may* be responsible

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for some portion of the condition) are actually *not* involved in producing (or perhaps co-producing through synergy) the condition being ascribed to the target cause - in the instant case, smoking. Notable in the formula for relative risk (a fundamental basis in the computation of attributable risk) is the identity of the disease or injury at issue and the degree of exposure to the presumptive cause of the disease or injury. The computation of a Smoking Attributable Fraction (SAF) then employs the result of the attributable risk computation.

Roberts' economic model uses the (SAF) as a critical element in its computation. The SAF requires for its computation, the smoking attributable risk. The smoking attributable risk requires for *its* computation, the relative risk of a smoking-related disease. The relative risk of a smoking-related disease requires for *its* computation, the incidence or prevalence of a smoking-related disease in a population and the numbers of persons in that population exposed (i.e. smokers). Roberts uses the estimates provided by John Dement who relied on the CPS-II data, with its inherent shortcomings (discussed below), to develop his SAFs for the NLEHTF. To compound the distance this may create between reality and fiction, Dement made no claim that they apply equally to any other population in any other state.

Inherent in the process of computing SAFs is the notion that attributable risk is the absolute incidence of a disease in exposed persons which can be attributed to that exposure and it is calculated by subtracting the incidence of a disease among non-exposed persons from its total incidence among exposed persons. To be suitably applied, attributable risk relies very heavily on the notion of ***all else being equal.*** The more potential alternative causes there are, the more difficult it becomes to ascribe absolute attribution. Consequently, when dealing with so-called tobacco related illnesses, because of the complexity of the intertwined multi-causal associations and long latency period, I believe it becomes very difficult to employ the relatively simplistic

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computation of attributable risk. Unless one is able to adequately control for or obviate the myriad number of potentially alternative causes of disease, one cannot really place much faith in attribution of a disease to any single factor.

The history of epidemiology includes numerous occasions in which, due to a variety of circumstances, misinterpretations and misrepresentations, the wrong conclusions were advanced. A particularly egregious example which comes to mind is the Love Canal - Dioxin incident near Niagra Falls in which pollution with more than 80 chemicals including dioxin by a local industry was blamed for conditions ranging from headaches and skin problems to cancer and intergenerational teratogenesis. The situation exploded into a major national crisis which raged some dozen or fifteen years with expenditures or commitments totaling more than $250 million, not to mention the turmoil of disrupting an entire community of Missouri families through relocation following discovery of dioxin contamination in the soil at Times Beach. Finally, around late 1990 or early 1991, Assistant Surgeon General Vernon Houk admitted that dioxin was not the threat it had originally been thought to be and he regretted having urged the evacuation of Times Beach some nine years earlier. It is situations like this that demand we be certain of our facts before taking draconian measures to prevent exposures, attenuate effects or demand restitution for issues affecting the public health.

LOGICAL & SCIENTIFIC FLAWS

In public health, decisions as to what beneficial health programs will be implemented, how they will be implemented and where they will be implemented are at the very core of health administration. Almost invariably budgets at any level, federal, state, county or city turn out to be lower than considered optimal by officials charged with responsibility to promote and work

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toward a healthy populace. Consequently it seems inevitable that competition will occur between programs for the scarce dollar, and the winner is usually the program which provides the most compelling statistics of need. The best statistics (i.e., the most convincing statistics) are those which are specific to the population to be served. Far less convincing are those collected in some larger population domain, especially those that are from a completely different population or venue.

In situations for which critical judgements or action with major or serious consequences may ensue, decisions should not be based on broad national statistics alone - there are many very personal data points which must be collected and assessed before such a decision can be reasonably made. Similarly, programs with major economic implications cannot be made on the basis of data which at best were designed for general program guidance. One would not place the retirement program investment of a huge corporation in some particular stock which seems to be doing well as one of several stocks comprising the Dow Jones Industrial average simply on the basis of the rise and fall of the Dow. Rather, one would dig deeply into the individual stock's performance and balance the result of that scrutiny against the risk the retirement fund is prepared to shoulder. The ramifications of being wrong are simply too dire to be approached in such a cavalier fashion. The same would hold true for circumstances in which decisions were to be made about who owes what to whom for real or imagined grievances such as in the current action regarding the NLEHTF payments for treatment of smoking-related diseases in the northwest.

In CPS II, nationally relevant data were sought but there appeared to be no intention to extrapolate or use these data below the National level, nor apparently was it anticipated that the data would be used (i.e., projected) below that level. Further, because of the unique character of

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the surveyed population, the CPS II data were only relevant for extrapolations to persons aged 30 or more in white households having at least one resident aged 45 or greater. Further, CPS II data are locked into a 6-year period, 1982-88. Plaintiffs in this action however, seek damages for at least the 28 year period 1979-2007. Year by year however, the demographic characteristics of almost all populations change, and what was measured in 1982 cannot be applied with any assurance of reliability to a population some 20 or more years later. Age, race, income, diets, lifestyles, morbidity and mortality patterns and other configurations are constantly changing and the further a researcher strays from the test year, the less likely the demographics of the test year will match the population for which the researcher would like to draw conclusions.

The CPS II survey, as is typically the case for most national surveys was conducted for general research purposes or for program guidance, and not for definitive, precise expenditure proposals (or in the present case, attributable damage estimates). For example, during my tenure as Director of Epidemiology for the Consumer Product Safety Commission (CPSC), I drew on my own understanding of general surveys and data sets, the health care delivery system, and the distribution of injuries to set general policy direction for the agency. I knew that precise data were unnecessary to make these policy decisions. However, two or three years down the line when the time came to commit specific dollar amounts to remedial projects, broad national surveys were wholly inadequate to form a basis for committing funds or taking specific rule making actions.

The question becomes then, what would be adequate for specific commitments of resources or reliable damages estimates? The answer is a data set that specifically addresses the

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problem at hand. If the data set does not exist, it must be created. When I was with the CPSC, we needed reliable data on the occurrence of injuries in the United States. I knew broad national health surveys such as the National Health Interview survey, the National Ambulatory Care Survey and the National Health and Nutrition Examination Survey (NHANES) , which were general policy surveys commonly used by several government agencies, were unacceptable because any regulation supported only by these surveys could not pass agency, judicial or industry criticism. This is because these surveys are imprecise and do not measure the correct variables for the specific issues in the rule making process. Accordingly, we set up at the CPSC a specific, targeted data collection system for injury measurement through a set of statistically representative hospital emergency rooms, which we called the National Electronic Injury Surveillance System (NEISS). NEISS was specific to the issue. It was ongoing and consisted of reporting units (hospital emergency rooms) located in the places where the data needed to be measured. As one CPSC Commissioner once noted, the NEISS was the only "actionable" data collection system ever seen in government where data obtained one day could be used to take action of the next day.

But even the NEISS, which was a national hospital survey, had its limitations. NEISS could not be used to make conclusions about injury patterns in specific states or even regionally, because it was not designed to be state specific. As designed, NEISS was incapable of measuring below the national level. The same limitation holds for CPS II.. The data or relationships drawn from CPS II cannot be applied to a sub-national population. This is why one cannot take national policy data and apply it to take specific remedial action or to estimate actual medical care costs in a state population, much less a subpopulation such as the NLEHTF population in a three-state area of the Northwest.

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From an epidemiological viewpoint, there are also flaws inherent even in the way the sample was drawn for the CPS II survey. Thousands of volunteers for the American Cancer Society recruited friends, neighbors and acquaintances to enroll their households as reporting units if their household included at least one person 45 years of age or greater. All persons in the household aged 30 or greater became subjects of the survey. The resulting study population was 93 percent white and far better educated than the national population (36 percent of the men had college or graduate degrees versus less than 20 percent for men & women combined, nationally). It is not unreasonable therefore to expect that they are also more affluent than the national population. This is hardly a population one would select to represent members of a labor union.

Self-reporting is another major source of potential data error in CPS II. Memory decay is a problem that increases as time passes; even a week or a month will result in decreasingly reliable information upon recall. Self-reporting also involves a potential problem through digital preference. For example, when the surveyor asks a subject "how old is your home." There is a tendency for the subject to round to the nearest 5 years. Similarly, when asked her age, a woman will frequently round down, while males typically round to the nearest year. The point is that self-reported data decreases the precision of the survey results, and good researchers only allow the use of this sort of data when precision is not important. Any estimates relying on these types of data has to be viewed with some skepticism. .

SYNTHETIC ESTIMATION

The act of using large population estimates in smaller elements of that same population is frequently called synthetic estimation. National data can be used at lower geopolitical levels

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when certain conditions exist. These conditions can exist when, and only when the national sample also takes into account the statistical representativeness of the lower level subsample's population at each subsample level for which estimates are to be extrapolated. That is, for example a state's portion of the total national sample must be an accurate representation of that state's demographic profile. Exposures and other relevant factors bearing on the state's population must also be proportionately and accurately represented in the national sample, or be capable of accurate adjustment to accommodate differences.

In the current action, appropriate conditions do not exist in the CPS II survey the NLEHTF is using in its damages model. The CPS II was never designed to even approximate any population below the national level. Neither was it purported to approximate any state-specific general population - much less any state subpopulation group such as the union membership in a state or group of states.. Therefore, CPS II should not be used by the NLEHTF to make estimates about its own population from relationships established through CPS II data. The act of using large population estimates in smaller elements of that same population is frequently called synthetic estimation.

Reliance on synthetic estimation procedures to construct estimates for areas smaller than the lowest level for which a sample was designed cannot be considered good science, particularly in high stakes issues such as the determination of who pays whom, how much and for what reason. This technique was first introduced by the National Center for Health Statistics (NCHS) about 30 years ago as a means to estimate characteristics of finite populations in subdomains of larger groups; for example, age groups within a school population or states within the nation. It was apparently used by NCHS in 1968 for the derivation of state level disability estimates, and later subjected to some evaluation reviews but little actual application. According

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to Laake in his paper "A Predictive Approach to Subdomain Estimation in Finite Populations" (JASA, June 1979), synthetic estimators may range from simple application of domain means to each subdomain, all the way to highly sophisticated procedures in which unbiased estimators are constructed for actual characteristics within post strata, and weighted sums of subdomains are generated in which the weights are the relative sizes of poststrata within the subdomains. It seems axiomatic that the greater the need for accuracy and reliability, the greater the need for using a more sophisticated synthetic estimation model. The importance of the instant issue dictates a rigorously greater attempt at precision and reliability.

SMOKERS V. NON-SMOKERS

Because the Plaintiff's model uses smokers and non-smokers with little additional qualification beyond age, sex, education and working status, it is important to note also that smokers and non-smokers differ in many substantive ways. Many of these differences may themselves account for a considerable amount of what is otherwise classified as smoking-related disease in populations, including the union membership of the NLEHTF. Some of the major differences are listed in the following table, which also gives a representative citation.

Smokers Compared to Non-Smokers

Characteristic	Citation
Greater risk takers	Jenks, RJ. Attitudes, perceptions, and risk-taking behaviors of smokers, ex-smokers and non-smokers. *J. of Soc. Psy.* Vol. 132(5), Oct. 1992, 569-575.
Use seat-belts less often	Jordan, BE, Perry, Ar. Health-risk behavior and the Type A behavior pattern. *Psychological Reports.* Vol. 61(3), Dec 1987, 963-966.
Smokers are more likely to engage in high-risk behavior; I.e. using marijuana, drinking heavily, and having multiple sex partners.	Emmons, KM et.al. Predictors of smoking among US college students. *Am. J. of Public Health.* Vol. 88(1), Jan 1988, 104-107.

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Female smokers were more sexually active	Pederson, L, Stavraky, K. Relationship or smoking to lifestyle factors in women. *Women & Health.* Vol. 12(2), 1987, 47-66.
Lower propensity to seek prenatal care	Zimmer, MH & M. Socioeconomic determinants of smoking behavior during pregnancy. *Social Science Journal.* Vol. 35(1), 1988, 133-142.
Lower value of a healthy lifestyle	Rose, JS et. al. Demographic factors in adult smoking status: Mediating and moderating influences. *Psy. of Add. Behav.* Vol.10(1), Mar 1996, 28-37.
Lower Median BMI	Smoking and relative body weight: An international perspective from the WHO MONICA Project. *J. of Epidemiology and Community Health.* Vol. 51(3), Jun 1997, 252-260.
Lower scholastic performance in high school	Borland, BL, Rudolph, JP. Relative effects of SES, parental smoking and poor scholastic performance on smoking among HS students. *Social Science & Med.* Vol. 9(1), Jan 1975, 27-30.
Less- educated	Lanz, PM et. al. Socioeconomic factors, health behaviors, and mortality: Results from a nationally representative prospective study of US adults. *JAMA.* Vol. 279(21), Jun 1998, 1703-1708. ***Also,*** Rose, et. al. (1996).
Have a lower SES	Zimmer, MH & M. Socioeconomic determinants of smoking behavior during pregnancy. *Social Science Journal.* Vol. 35(1), 1988, 133-142. ***Also,*** Borland, Rudolph (1975).
Lower levels of income	Lanz, PM et. al. Socioeconomic factors, health behaviors, and mortality: Results from a nationally representative prospective study of US adults. *JAMA.* Vol. 279(21), Jun 1998, 1703-1708.
Less participation in athletics	Emmons, KM et.al. Predictors of smoking among US college students. *Am. J. of Public Health.* Vol. 88(1), Jan 1988, 104-107.
Whites have a higher prevalence than Blacks.	Flint, A. Novotny, T. Trends in Black/White differences in current smoking among 18 to 24 year-olds in the United States, 1983-1993. *Am. J. of Prev. Med.* Vol 14(1), Jan 1998, 19-24.
Among college students: Women are more likely to smoke	Emmons, KM et.al. Predictors of smoking among US college students. *Am. J. of Public Health.* Vol. 88(1), Jan 1988, 104-107

THE CONSERVATIVE NATURE OF ESTIMATES

Mr. Roberts avers that the process he employed in generating smoking attributable healthcare expenditures produces reasonable, but conservative results. To justify this claim he lists five reason. However legitimate any of the five reasons he gives may be if the data base itself were relevant, the fact remains that the data base itself was sufficiently flawed for all the reasons discussed earlier in this paper that it is useless for the purpose Mr. Roberts intended. Accordingly, I reject the notion that his estimates are either reasonable or conservative.

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REMUNERATION

I am being compensated at the rate of $300 per hour for non-testimony time and at a flat rate of $3,000 per day or portion thereof for deposition or trial testimony.

Respectfully submitted September 10, 1998

Robert D. Verhalen, Dr.P.H.

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ATTACHMENT A

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EDUCATION

- **State University of Iowa BA (Zoology/Parasitology)**
- **University of North Carolina MPH (Health Administration)**
- **University of North Carolina Dr.P.H. (Epidemiology)**

EMPLOYMENT RECORD

- **President, Verhalen & Associates, McLean, VA (Current)**

  Litigation Support, Research and consultation, specializing in trauma epidemiology. Capabilities include investigation in 105 countries, product-related hazard analysis and consultation, evaluation of regulatory analyses conducted by federal agencies, product testing, comparative risk analysis, liability and safety analysis, human factors analysis, cost benefit analysis and assistance in case development for litigation through expert testimony, video documentation, and case related documentation management systems.

  Board Chairman and CEO, Docutrol, Inc., McLean, VA (Current)

  High speed, Digital imaging and indexing service nationwide for attorneys, financial institutions, research organizations and other document or records-intensive companies.

- **Associate Executive Director**
  U.S. Consumer Product Safety Commission (22 years)

  Designed and directed through four subordinate divisions all statistical, epidemiological, and Human Factors studies and research for the Agency. As Director of Epidemiology, ensured proper interpretation of statistical and other research data for and by three to five presidentially appointed commissioners. Developed and defended annual budget for Directorate. Represented the Agency at international meetings involving issues focusing on statistics, epidemiology, and data collection. Collaborated with other technical units of

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the Commission on the development and evaluation of remedial strategies. Set statistical and research policy for the Agency and coordinated analytical activities with other Federal agencies.

Major Accomplishments:

Established Commission's reputation for scientific integrity and quality data for use by sister agencies. Refined the National Electronic Injury Surveillance System (NEISS) to to enable its use for the collection of injury data by other Federal agencies and as a model for other surveillance systems developed in its image throughout the modern world.

- **Assistant Director, Injury Data and Control Center**
  Bureau of Product Safety, FDA, USDHEW (1 year)

Planned and directed development and refinement of the Bureau's statistical, economic, analytic and research programs to provide incidence and prevalence data on injuries.

Major Accomplishment:

Established sufficient credibility of the Bureau's methods for the study of product-related injuries to instigate the transfer of its systems to the new Consumer Product Safety Commission.

- **Chief, Epidemiology Branch, Division of Product**
  Safety, Bureau of Product Safety, FDA, USDHEW (1 year)

Planned and directed development of the Bureau's data collection programs. Directed multi-disciplinary analysis of hazard and injury data. Liaised with other agencies, and official groups representing the fields of medicine, public health, statistics, engineering and economics.

Major Accomplishment:

Developed the National Electronic Injury Surveillance System (NEISS) embodying unprecedented timeliness, statistical precision, national representation and operating flexibility.

- **Director, Task Force on Injury Identification**
  National Commission on Product Safety (PL90-146) (1 year)
  Led research for Presidential Study Commission to determine the scope and magnitude of the product-related injury problem in the United States.

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Major Accomplishment:

Documentation was sufficiently compelling to be instrumental in convincing the President and Congress to create the U.S. Consumer Product Safety Commission.

◆ **Other Relevant Positions:**

Instructor,Injury Prevention Program, School of Public Health, UNC-CH (2 years)

Senior Research Associate, North Carolina Highway Safety Research Center, UNC_CH (1 year)

◆ **Other Relevant Positions (cont.):**

Safety Management Consultant, Housing Hygiene & Accident Prevention Section, GDPH (1 1/2 years)

Sanitarian & Safety Programs Representative, Lake County, IL

MEMBERSHIPS:

Society for Epidemiologic Research
American College of Epidemiology
American Statistical Association
American Public Health Association
Editorial Board for Journal of Safety Research

AWARDS:

FDA Certificate of Merit
Chairman's Award for Excellence
Chairman's Special Citation for Superior Service
Chairman's Nomination for SES Executive Excellence Award
Chairman's Award for Distinguished Service

REFERENCES WILL BE PROVIDED UPON REQUEST

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ATTACHMENT B

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STATE OF MINNESOTA

COUNTY OF RAMSEY

DISTRICT COURT

SECOND JUDICIAL DISTRICT

Case Type: Other Civil

THE STATE OF MINNESOTA,

BY HUBERT H. HUMPHREY, III,
ITS ATTORNEY GENERAL,

COURT FILE NO. C1-94-3565

and

BLUE CROSS AND BLUE SHIELD
OF MINNESOTA,

Plaintiffs,

vs.

PHILIP MORRIS INCORPORATED,
R. J. REYNOLDS TOBACCO COMPANY,
BROWN & WILLIAMSON TOBACCO CORPORATION,
B.A.T. INDUSTRIES P.L.C.,
BRITISH-AMERICAN TOBACCO COMPANY LIMITED,
BAT (U.K. & EXPORT) LIMITED,
LORILLARD TOBACCO COMPANY,
THE AMERICAN TOBACCO COMPANY,
LIGGETT GROUP, INC.,
THE COUNCIL FOR TOBACCO RESEARCH - U.S.A., INC., and
THE TOBACCO INSTITUTE, INC.,

Defendants.

- Epidemiology

Defendant's Expert Report of:

Robert D. Verhalen, Dr.P.H.

July 1, 1997

CONFIDENTIAL – SUBJECT TO MINNESOTA PROTECTIVE ORDER

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Defendants' Expert Report
of
Robert D. Verhalen, Dr.P.H.
July 1, 1997

QUALIFICATIONS

My name is Robert Donald Verhalen. I presently reside in [DELETED] where I am President of Verhalen & Associates (VAssoc), a consulting and litigation support firm. VAssoc is built around my 22 years directing the epidemiology functions of the U.S. Consumer Product Safety, initially as Director of its Bureau of Epidemiology and later as Associate Executive Director of the Commission. My Curriculum Vitae which appears at Appendix A. details my background and experience in more systematic format.

I received my BA degree from the State University of Iowa at Iowa City in Zoology (with a concentration in Parasitology) in August 1963. Following a year with a local public health department in Northern Illinois, I received my Masters Degree in Public Health from the Department of Health Administration at the School of Public Health at the University of North Carolina, Chapel Hill in August 1965.

After roughly a year and a half with the State Department of Health in Georgia, and nine months at the North Carolina Highway Safety Research Center, I entered the doctoral program in the Department of Epidemiology at the UNC School of Public Health. There, while working for two years as an instructor in the Department of Health Administration (and concurrently for the second year of that appointment, as Task Force Chief on a National Presidential Study Commission , The National Commission on Product Safety [NCPS]), then as an Epidemiology

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my retirement from federal service in April 1995

While acting as CPSC's principal survey scientist, I led the continued refinement of the NEISS to its present status as the preeminent ongoing trauma surveillance system in the Federal Government, serving several other federal agencies such as FDA, The Department of Transportation (DOT), the Environmental Protection Agency (EPA), The Centers for Disease Control (CDC - two units, the National Institute for Occupational Safety and Health [NIOSH], and the National Center for Injury Prevention and Control [NCIPC]), The Department of Housing and Urban Development (HUD), and the Department of Justice (DOJ). These interagency alliances not only met critical data needs of many of the receiving agency's programs, but they saved millions in tax dollars by obviating the need for each agency to develop and operate ad hoc systems to meet their analytic program requirements.

In 1973 I was appointed as CPSC's representative to the Working Group on Fire Data Analysis for the International Standards Organization (ISO), being elected Chairman of that 12-nation group later the same year and leading the development of consensus standards for the analysis of fire statistics among member nation scientists. In the late seventies, I was appointed to the Epidemiology Working Group of the Interagency Regulatory Liaison Group (IRLG), a body created to standardize methods and criteria for the promulgation of national standards and regulations to the maximum practical extent among FDA, EPA, CPSC, the Department of Labor's Occupational Safety and Health Administration (OSHA) and the Department of Agriculture's Food Safety and Quality Service (FSQS). As the elected Chairman of this group of scientists I led the creation of the "Guidelines for Documentation of Epidemiological Studies," designed to improve the ability of these regulatory bodies to assess the quality of science

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employed in studies submitted in support of regulatory action.

From the late seventies until 1990 I served on the Interagency Committee of Federal Executive Scientists advising on the preparations for the 1980 and 1990 Decennial Census of the Population From the mid-eighties until around 1990 I served as a member of the U S. Study Committee of the World Health Organization (of the United Nations) on preparation of the 10th Revision of the International Classification of Disease and Accidents. Throughout my 25-year career as a government scientist I have been called upon several occasions to consult with scientists and other officials representing foreign governments as they endeavored to develop surveillance systems to permit the study of injuries in their own country, e.g., Europe's Organization for Economic Cooperation and Development (OECD), the Commission of European Communities in Brussels, the Nordic Council of Ministers, Japan, Canada, Australia and the United Kingdom.

Upon retiring from federal service in April 1995, I opened Verhalen & Associates, a consulting firm created to assist private parties in accessing, understanding and using public data.

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INTRODUCTION

My testimony and opinions will be based upon my academic training, twenty-five years as a practicing epidemiologist, the scientific literature on issues relating to methodological aspects of population based research and literature on illnesses associated with smoking. In addition I have reviewed a substantial body of literature surrounding the surveys and models employed in the Minnesota Smoking Attributable Health Care Expenditures by Blue Cross/Blue Shield of Minnesota and the State of Minnesota, 1978-1996.

I have also reviewed the Report of the Advisory Committee to the Surgeon General, 1964 and the Report of the Surgeon General, 1989; the National Medical Expenditure Survey (NMES II); NMES Research Findings and associated articles; the Center for Disease Control - Behavioral Risk Factor Surveillance Survey (BRFSS) Methods, Procedures and reported State Data; The Center for Disease Control - Smoking-Attributable Mortality, Morbidity, and Economic Costs Models: SAMMEC II and SAMMEC 2.1; relevant data from the Bureau of Census Population Survey (CPS) and the CPS Tobacco Use Supplement (TUS); the International Agency for Research on Cancer (IARC) Monograph on Tobacco Smoking, and the American Cancer Society Cancer Prevention Study (CPS II).

In addition, I have reviewed the U.S. Cancer Mortality Rates and Trends, 1950-1979, EPA, September 1983, Vols. 1-IV, selected and derived cancer mortality rate trend data and charts from Vols. I through IV. And I have reviewed the deposition and exhibits for Leonard S. Miller, October 15-16, 1966 as well as his expert report (with others) of June 2, 1997 and the the Plaintiffs' Expert Report of Jonathan M. Samet, M.D., June 2, 1997.

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A listing of principal articles and documents I relied upon, not cited specifically above, is attached. My review of plaintiffs' material is necessarily ongoing because of its only recent availability and I may supplement this report as my review of these and other documents, including those yet to be produced by the plaintiff, are made available. I may also rely on the work and opinions of other experts in this case, and/or offer testimony in rebuttal to plaintffs' witnesses.

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SUMMARY OF OPINIONS

- The 1987 National Medical Expenditure Survey (NMES) was designed for policy making decisions on a National Level and cannot be indiscriminately used to determine causes of health care expenditures on just any population level.

- NMES documents state "...the goal of the Household Survey was to provide national estimates of the use of, and expenditures for health services and of health insurance coverage" for the civilian, noninstitutionalized United States population.

- The State of Minnesota attempts to use data from NMES and other policy surveys to construct a model which purports to calculate medical expenditures for a variety of diseases attributed to cigarette smoking.

- There are several logical and scientific flaws, from an epidemiological viewpoint, in the survey data employed in the model used by Minnesota to construct its model.

- There are times, when appropriate conditions exist, that national data can be used at the state level. These conditions do not exist with the surveys the State of Minnesota is using in its damages model.

- The population of Minnesota differs materially and substantially from the NMES national population.

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- Minnesota has a lower net migration rate than the national rate.
- Minnesota has a substantially lower proportion of its population living in urban or metropolitan areas than the nation as a whole.
- Household size decreased faster in Minnesota than in the nation as a whole berween 1980 and 1990.
- The overall death rate for Minnesota has been consistently below that of the nation as a whole berween 1980 and 1992.
- Death rates for heart disease, cancer and COPD are lower in Minnesota than for the national population (1992).
- Minnesota has a greater percent of residents covered by health insurance than the national population (1991-93).
- Minnesotans have a higher degree of educational attainment than the national population - nearly 20 percent more of the States' population holding 4-year college degrees (1990).
- Minnesota has a lower percentage of its residents who rely on public aid (AFDC and Federal Supplemental Security Income) than the national population (1990-93)

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- Minnesota has a higher employment level than the national population (1994).

- Minnesota has 23-33 percent fewer of its population living below the poverty level (1980-93).

- Many of the above factors were not measured in the NMES and Minnesota surveys.

- While the physiology of disease may remain the same nationwide, exposure to alternatively causal conditions do not. These are more often a function of factors such as geography, industrialization, urbanity, climate, culture, stress, and societal proclivities.

- Epidemiology has its limitations in the study of disease etiology and the attribution of risk

  - The concept of attributable risk cannot be readily applied to situations with intertwined, multi-causal associations and long temporal effects.

  - Because of the extensive number of both known and unknown risk factors for diseases classified as smoking-related, and the unidentified interactive relationships between these factors, the simplistic concept of attributable risk is inadequate to determine and attribute "cause" to any single factor.

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BASIS FOR OPINIONS

In public health, decisions as to what health beneficial programs will be implemented, how they will be implemented and where they will be implemented are the essence of health administration. Budgets at all levels, federal, state, county and city seem always lower than considered optimal to officials charged with responsibility to promote and work toward a health populace. Consequently it is invariable that struggles will take place between programs competing for the scarce dollar and the winner is most usually the program providing the most compelling statistics of need. The best statistics (i.e., the most convincing statistics) are those which are specific to the population to be served. Less convincing are those collected in some larger population domain, especially those that are from a completely different venue. Too often, since local studies are frequently no less expensive per unit of data than larger studies, local studies are not conducted and the program personnel turn to state or even national statistics to justify their proposed programs. In a very general sense, this is often not too problematic since, even if the precision of the data is somewhat off the mark for the local population, the difference is only quantitative, not qualitative. That is, if condition A ranks worst in the broader population while it ranks only second in the narrower group, the narrow groups program of amelioration for A may still be justifiable simply on the basis of its local impact and its visibility at the local level. On the other hand the condition which ranks first at the local level will usually not be ignored because it too will be too evident to pass over. In short, both will probably be addressed though perhaps not as well as either could have been if its amelioration program had been more adequately funded. The public health is enhanced in either event. Hence, the use of larger domain information, which was probably collected for "background" or general program guidance purposes, can frequently be used at the local level without serious repercussions.

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In situations however for which critical decisions or action with major personal or other ramifications are addressed in this fashion, serious consequences may ensue. Surgical decisions should not, for example, be based on statistics alone - there are many very personal data points which have to be collected and assessed before such a decision can be reasonably made. Similarly, programs with major economic implications cannot be made on the basis of data which at best were designed for general program guidance. One would not place the retirement program investment of a huge corporation in some particular stock which seems to be doing well as one of several stocks comprising the Dow Jones Industrial average simply on the basis of the rise and fall of the Dow. Rather, one would dig deeply into the individual stock's performance and balance the result of that scrutiny against the risk the retirement fund is prepared to shoulder. The ramifications of being wrong are simply too dire to be approached in such a cavalier fashion. The same would hold true for circumstances in which decisions were to be made about who owes what to whom for real or imagined grievances, as in the current action regarding Medicaid expenditures.

In the National Medical Expenditure Survey: Questionnaires and Data Collection Methods for the Household Survey and the Survey of American Indians and Alaska Natives - Methods 2, prepared for the Department of Health & Human Services by W. Sherman Edwards and Martha Berlin (DDHS Publication No. (PHS) 89-3450, the primary goal of the Household survey was to provide national estimates of the use of and expenditures for health services and of health insurance coverage among the civilian, non-institutionalized population of the United States. The four-stage sampling design employed in this survey yielded 165 primary sampling units (PSUs) and approximately 36,000 addresses to which screening interviews were to be addressed. Five rounds of interviews were conducted overall and a self-administered

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questionnaire was conducted between rounds one and two. This self-administered questionnaire was desiged to obtain "...broad information on health status and health practices" concentrating on habits, health "episodes," attitudes and perceptions.

Budget constraints forced the framers of this study into a rather complex design in which two distinct and separate data collection organizations (WESTAT, Inc. and NORC) drew independent national samples from which to collect data over the 18 month period from January 1987 to July 1988. The analytical goals specified that approximately 14,000 households in 100 separate geographic areas were to be completed, or an average of 140 households in each of the 100 geographic locations within the 50 states and the District of Columbia. Unbiased national estimates were sought which would have adequate precision down to the level of the four census regions. No need for precision below the level of these four census regions (e.g., at the state level) was ever articulated, nor apparently was it anticipated that the data would be used (i.e., projected) below that level. Indeed, among some 84 studies listed in an expert report submitted by plaintiffs' experts purporting to illustrate the broad utility of NMES, analysis at the state level was resoundingly absent.

Further, NMES data are locked into a single year, 1987, the year in which the NMES sample was studied. Plaintiffs however, seek damages for the 19 year period 1978-1996. Year by year however, the demographic characteristics of almost all populations change, and what was measured in 1987 cannot be applied with any assurance of reliability to a population some ten years earlier or later. Age, race, income, diets, lifestyles, morbidity and mortality patterns and other configurations are constantly changing and the further a researcher strays from the test year, the less likely the demographics of the test year will match the population for which the researcher would like to draw conclusions.

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Typically, national surveys are conducted by government agencies for general program guidance, and not for definitive, precise expenditure proposals (or in the present case, attributable damage estimates). For example, during my tenure as Director of Epidemiology for the consumer Product Safety Commission, I drew on my own understanding of general surveys and data sets, the health care delivery system, and the distribution of injuries to set general policy direction for the agency. I knew that precise data were unnecessary to make these policy decisions. However, two or three years down the line when the time came to commit specific dollar amounts to remedial projects, broad national surveys were wholly inadequate to form a basis for commiting funds or taking specific rulemaking actions. The documentation from NMES states forthrightly that it is to be used for national policy guidance only:

> The 1987 national medical survey was designed to provide an assessment of health services use, expenditures, sources of payment and health insurance coverage of the U.S. civilian non-institutionalized population. The scope and depth of data collection reflects the needs of government agencies, legislative bodies and health professionals for the comprehensive national estimates needed in the formation and analysis of national health policies.

The question becomes then, what would be adequate for specific commitments of resources or reliable damages estimates? The answer is a data set that specifically addresses the problem at hand. If the data set does not exist, it must be created. When I was with the CPSC, we needed reliable data on the occurrence of injuries in the United States. I knew broad national health surveys such as the National Health Interview survey, the National Ambulatory Care Survey and the National Health and Nutrition Examination Survey (NHANES), which were general policy surveys commonly used by several government agencies, were unacceptable because any regulation supported only by these surveys could not pass agency, judicial or

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industry criticism. This is because these surveys are imprecise and do not measure the correct variables for the specific issues in the rulemaking process. Accordingly, we set up at the CPSC a specific, targeted data collection system for injury measurement through a set of statistically representative hospital emergency rooms, which we called the National Electronic Injury Surveillance System (NEISS). NEISS was specific to the issue. It was ongoing and consisted of reporting units (hospital emergency rooms) located in the places where the data needed to be measured. As one CPSC Commissioner once noted, the NEISS was the only "actionable" data collection system ever seen in government where data obtained one day could be used to take action of the next day.

But even the NEISS, which was a national hospital survey, had its limitations. NEISS could not be used to make conclusions about injury patterns in specific states or even regionally, because it was not designed to be state specific. As designed, NEISS was incapable of measuring below the national level. The same limitation holds for NMES. The data or relationships drawn from NMES cannot be applied to a state. This is why one cannot take national policy data and apply it to take specific remedial action or to estimate actual medical care costs in a state population, much less a subpopulation such as the Minnesota Medicaid population.

Claims that a national survey is the principal data source in the United States for analyses of some problem are often supported by the notion that because Congress or some other national body (e.g., FDA, DOT, EPA) uses the data, it is necessarily sufficiently precise, correct and appropriate. Based upon more than 25 years experience as a government executive and scientist, I believe nothing could be further from the truth. For example, the Consumer Product Safety Commission (CPSC), an independent federal regulatory agency (which makes it actually a part

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of the legislative branch of Government rather than the Executive branch), set out in the early 1980s to reduce lead in paint by setting a standard for maximum allowable lead levels. After more than a year of collecting data, assaying paint chips, conducting animal tests, reviewing the literature and collaborating with other scientists engaged in similar research, CPSC concluded insufficient data simply did not allow the establishment of a safe level. That is, the Commission could not identify a level below which it could be assured no adverse effects would occur. The Congressional oversight committee however, expressed frustration with the agency and proceeded to use Commission material to propose its own standard, subsequently passing legislation setting the level at 0.06 percent. To this day, no further data have surfaced which would permit one to say there is any measurable degree of safety at this level. Claims by the plaintiffs then that NMES is the primary source of data in the United States, and is used by Congress among others as a basis for action, is scant support for the legitimacy of its use by Minnesota in its model for estimating state costs of smoking attributable disease.

NMES DATA

From an epidemiological viewpoint, there are flaws inherent in the NMES survey data due to self reporting of information and lack of correlation between medical provider reports and respondent reports of medical conditions. Self-reporting of information in surveys is a major source of potential data error in NMES. Memory decay is a problem that increases as time passes; even a week or a month will result in decreasingly reliable information upon recall. The NMES authors may have been unconcerned with memory decay because, as just discussed, NMES was designed to be a general population survey conducted for application to policy concerns. Again, NMES documentation states that "...addition of self-administered questionnaires to the NMES Household Survey and SAIAN was intended to obtain broad

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information on health status and health practices." Further, self-reporting involves another problem: digital preference. This, for example, is the case when the surveyor asks a subject "how old is your home," there is a tendency for the subject to round to the nearest 5 years. Similarly, when asked her age, a woman will frequently round down, while males typically round to the nearest year. The point is that self-reported data decreases the precision of the survey results, and good researchers only allow the use of this sort of data when precision is not important. This is especially important due to the extensive use of the NMES self-administered health status questionnaire in developing the plaintiff's model to estimate smoking attributable expenditures. Any estimates relying on this type of data cannot be considered reliable.

Another shortcoming of NMES for purposes of obtaining reliable data is the lack of correlation between medical provider reports and respondent reports of medical conditions. The poor correlation indicates that subjects' self-reported responses were very inaccurate. For example, the probability of agreement between respondents and physicians about the incidence of cancer of any kind in the respondents was only 50%, and the probability of agreement between providers and respondents regarding the occurrence of heart attacks was only 39%. For arteriosclerosis the correlation of agreement was only 31%, less than one in three. This lack of correlation creates further imprecision which makes it impossible to use these data as a source on which to make definitive judgments or reliable estimates. The authors of the Minnesota model use the responses from questions on the self-reported history of diseases in their model. As demonstrated above, the responses are wholly inadequate for a model of this nature. Further, if one ignores the subject self-reported responses in favor of medical provider reported responses about conditions, reliable results are still not likely due to potential inaccuracies of the provider information. Based on my experience, physicians often put information on the record for non-

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diagnostic reasons such as to justify proper treatment that might be authorized by third party payers under one diagnosis but not another.

SYNTHETIC ESTIMATION

National data can be used at the state level when certain conditions exist. These conditions can exist when, and only when the national sample also takes into account the statistical representativeness of the state subsample's population at each subsample level for which estimates are to be extrapolated. That is, the state's portion of the total national sample must be an accurate representation of that state's demographic profile. Exposures and other relevant factors bearing on the state's population must also be proportionately and accurately represented in the national sample, or be capable of accurate adjustment to accommodate differences.

In the current action, appropriate conditions do not exist among the surveys the state of Minnesota is using in its damages model. The NMES was never designed to even approximate any population below the level of the four census regions of the Nation. Nor was it ever intended to approximate any state-specific general population - much less any state subpopulation group such as the indigent population of the state. Therefore, NMES should not be used by Minnesota as justification for claiming that it can make reliable estimates about its own population from relationships established with it. The act of using large population estimates in smaller elements of that same population is called synthetic estimation.

Reliance on synthetic estimation procedures to construct estimates for areas smaller than the lowest level for which a sample was designed also seems somewhat chancy, particularly in high stakes issues such as the determination of who pays whom, and how much. This technique was first introduced by the National Center for Health Statistics (NCHS) about 30 years ago as a

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example, age groups within a school population or states within the nation. It was apparently used by NCHS in 1968 for the derivation of state level disability estimates, and later subjected to some evaluation reviews but little actual application. According to Laake in his paper "A Predictive Approach to Subdomain Estimation in Finite Populations" (JASA, June 1979), synthetic estimators may range from simple application of domain means to each subdomain, all the way to highly sophisticated procedures in which unbiased estimators are constructed for actual characteristics within post strata, and weighted sums of subdomains are generated in which the weights are the relative sizes of poststrata within the subdomains. It seems axiomatic that the greater the need for accuracy and reliability, the greater the need for using a more sophisticated synthetic estimation model. Accordingly, it is inappropriate to casually pass off the application of such a sophisticated concept as "...it is essentially what we do to estimate smoking attributable expenditures in Minnesota." Interestingly, Miller, et al. provide no indication they employed any but the simplest method (direct estimation downward) of "synthetic estimation." The importance of the issue dictates a greater attempt at precision and reliability.

QUALITY OF REPORTING

Good research includes the reporting of research findings. It is axiomatic that good reporting of research findings includes documentation of the methods and procedures by which the research was conducted. One may summarize this notion by stating good science requires good documentation. Only with adequate documentation may other scientists who rely on such reports properly evaluate the quality and strength of previously reported findings. Then, over time, scientific understanding grows and knowledge advances.

In the late 1970s, government epidemiologists in several federal agencies, noting

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prepared "Guidelines for the Documentation of Epidemiologic Studies". Following considerable dialogue with other scientists in both the public and private sector to attain consensus, these guidelines were published in the American Journal of Epidemiology (AJEP) in 1981. The intent of the guidelines was to insure that when important policy and programmatic decisions were at stake, methods and procedures of the submitted studies could be subjected to rigorous scrutiny or replicated if necessary. A joint committee of the scientific community representing the Society for Epidemiologic Research and the Epidemiology Section of the American Public Health Association in a companion article (Commentary: The Interagency Regulatory Liaison Group "Guidelines...,AJEP, November 1981) agreed that "few epidemiologists would deny that deficiencies sometimes occur," while cautioning that the guidelines should not become *law*, nor be used as an excuse to throw out studies not meeting the minimum guidelines. They generally acceded however to the principle that good documentation is an inherent part of good science.

ATTRIBUTABLE RISK

Minnesota's estimates of the cost of medical care rely heavily on the concepts of attributable fractions and attributable risk. These concepts, however cannot be indiscriminately applied to situations with intertwined multi-causal associations without risk. The epidemiologic concept of attributable risk, while flexible to the extent that it may apply to accidental injury as readily as to contagious or chronic disease conditions, requires for its computation, data on the incidence or prevalence rates of specific conditions among both exposed and non-exposed individuals in a population. Notable in the formula for relative risk (a fundamental basis in the computation of attributable risk) is the identity of the disease or injury at issue and the degree of exposure to the presumptive cause of the disease or injury. The computation of a Smoking Attributable Fraction (SAF) then employs the result of the attributable risk computation.

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element in its computation. The SAF requires for its computation, the smoking attributable risk. The smoking attributable risk requires for its computation, the relative risk of a smoking-related disease. The relative risk of a smoking-related disease requires for its computation, the incidence or prevalence of a smoking-related disease in a population and the numbers of persons in that population exposed (i.e. smokers)

Inherent in this process is the notion that attributable risk is the absolute incidence of a disease in exposed persons which can be attributed to that exposure and it is calculated by subtracting the incidence of a disease among non-exposed persons from its total incidence among exposed persons. To be suitably applied, attributable risk relies very heavily on the notion of all else being equal. The more potential alternative causes there are, the more difficult it becomes to ascribe absolute attribution. Consequently, when dealing with so-called tobacco related illnesses, because of the intertwined multi-causal associations and long latency period, I believe it becomes very difficult to employ the relatively simplistic computation of attributable risk. Unless one is able to adequately control for or obviate the myriad number of potentially alternative causes of disease, one cannot really place much faith in attribution of a disease to any single factor.

MINNESOTA IS DIFFERENT

From an epidemiologic standpoint, if one intends to ascribe data on any critical characteristic from one population to another, it is necessary for both populations to be as much alike as possible. Minnesota is in several meaningful ways different from the National population.

Net migration affected the state of Minnesota differently than it did the Nation as a whole. Minnesota being considerably slower in its growth. According to figures from the

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of the National rate (respectively) for a net growth of 14.5% overall against 21.2 % for the Nation. In 1993, immigrants to Minnesota were predominantly from the orient (China and Vietnam) or the Soviet Union (12%, 11% and 13% respectively) whereas for the Nation, these three sources of immigration accounted for only 20% (7%, 7% and 6% respectively). By far the fastest growing immigrant population in the United States is Hispanic, principally from Mexico. Minnesota is considerably more white than the Nation and it stands currently at approximately 2% black in its population complexion as against 15% for the Nation as a whole.

Only 66% of the Minnesota population resided in metropolitan areas as opposed to more than 78 % for the Nation through the 1980s, 31% actually living in what were classified as rural areas of the State (as against only 24.8% living rurally for the Nation as a whole). Overall, Minnesota households decreased in size from 2.68 persons per household in 1980 to 2.55 per household in 1990. While there was also a decrease in household size nationally, the rate fell from 2.75 to 2.63, or only 67% of the decline seen in Minnesota.

The overall death rate in Minnesota has stayed consistently below the national death rate between 1980 and 1992, averaging 7% below the national rate for the period. In particular, the death rates for heart disease, cancer and chronic obstructive pulmonary disease are lower in Minnesota, heart disease death rates being 18% lower in 1992 and the others being 6% lower and 7% lower respectively for 1992. Cerebrovascular disease and atherosclerosis on the other hand were 12% and 13% higher (in 1992 and 1991 respectively). Nationally, 67% more persons were without health insurance coverage than in Minnesota, averaging fully 15.2% without coverage nationally for 1992-93.

Minnesotans are more highly educated than the national average with 19 % of the States' population holding bachelor's degrees in 1990 and 39% more Minnesotans holding and

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public aid (AFDC and Federal Supplemental Security Income) than citizens nationally (25% fewer in 1990 and 29% fewer in 1993). Further, 34% fewer Minnesotans were unemployed in 1994 than was the case nationally and 23% to 33% fewer of the states' residents were living below the poverty level than was the case nationally between 1980 and 1993

These factors were largely ignored in the collection of data under the NMES, the Behavioral Risk Factor Surveillance System (BFRSS), the National Health and Nutrition Examination Survey (NHANES), and the NHANES I Epidemiologic Follow-up Study (NHEFS). These differences obviate the use of *any* of these surveys in the Minnesota model to estimate smoking attributable costs.

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